CARDIOVIT AT-60

Operating Manual APPENDIX

Version 3.2

SCHILLER

THE CHALLENGE OF MEDICAL TECHNOLOGY

SCHILLER

CARDIOVIT AT-60

Operating Manual APPENDIX

Version 3.2

SCHILLER
AMERICA

3002 Dow Avenue
Building 138
Tustin, CA 92680
(714) 730-4900
Fax (714) 730-0650
(800) 247-8775

Art.-No.: 2.510152
Issue: November 1994

Terms of Warranty

The CARDIOVIT AT-60 is warranted against defects in material and manufacture for the duration of one year (as from date of purchase). Excluded from this guarantee is damage caused by an accident or as a result of improper handling. The warranty entitles free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorized or unqualified persons attempt to make repairs.

In case of defect, send the apparatus post-paid to your dealer or directly to the manufacturer.

The manufacturer can only be held responsible for the safety, reliability, and performance of the apparatus if:

- assembly operations, extensions, re-adjustments, modifications, or repairs are carried out by persons authorized by him, and
- the CARDIOVIT AT-60 is used in accordance with the operating instructions.

Appendix to Operating Manual AT-60

TABLE OF CONTENTS

Short Information of Available Options

Option 1 SCHILLER ECG Measurement Program (M)

Option 2 SCHILLER ECG Interpretation Program (C)

Option 3 Frank Vectorcardiography

Documented in Chapter 5 in "Operating Manual CARDIOVIT AT-60"

Option 4 EXEC Analysis Programm for Exercise ECGs

Option 5 Pacemaker Measurements

Option 6 Pulmonary Function Testing

Option 7 Late Potential Analysis

Option 8 Heart Rate Variability

Option 10 Floppy Disk Drive

Options

Short Information

CONTENTS

Hardware Options

SCHILLER TM 400S Treadmill

The ideal treadmill for exercise testing.

SCHILLER ERG 1

The bicycle for optimal completion of your ergometry measurement site. The load range is between 25and 999 W.

Video Monitor

Increases the flexibility of viewing an ECG recording by means of a remote video display.

3.5" Floppy Disk Drive

The ideal media to archive up to 220 ECGs in one 1.44 MB diskette (documented in "User Manual CARDIOVIT AT-60").

The storage capacity depends upon data selection. Resting ECGs, exercise ECGs, late potential analyses, heart rate variability analyses as well as pulmonary function tests can be stored to diskette.

Software Options

SCHILLER Measurement Program (M)

Software upgrade providing additional measurement program for resting and exercise ECGs
(see Option 1).

SCHILLER Interpretation Program (C)

Software upgrade providing additional measurement and interpretation program for resting ECGs
(see Option 2).

Vectorcardiography (VM, VC)

Software upgrade for the plotting of vector loops (saggital, frontal and horizontal) based on the Frank XYZ leads
(documented in "User Manual CARDIOVIT AT-60").

In order to use this option, option 1 "Measurement Program (VM)" or option 2 "Interpretation Program (VC)" have to be installed.

EXEC Analysis Program for Exercise ECGs

Provides continual construction of average complexes, ST measurements and rhythm analysis, probability of coronary artery disease (CAD) together with a comprehensive final report
(see Option 4).

Pacemaker Measurement

Software for the measurement of stimulation intervals and duration for both single and dual-chamber pacemakers
(see Option 5).

Late Potential Analysis

Program especially designed for the detection of prolonged electrical activity after depolarisation
(see Option 7).

To use this option, the option 1 "Measurement Program (M)" and option 2 "Interpretation Program (C)" have to be installed.

Heart Rate Variability

Special program for detection and analysis of the variability of RR intervals
(see Option 8).

To use this option, the option 1 "Measurement Program (M)" and option 2 "Interpretation Program (C)" have to be installed.

Special Options

Pulmonary Function

Software for the recording, evaluation and printout of four modes for the Testing measurement and calculation of inspiratory and expiratory values with visual presentation of all tests and clearly documented test results in conjunction with the SP-100 or SP-160 flow sensor
(see Option 6).

Flow Sensor SP-100, SP-160

Flow sensors especially designed for pulmonary function testing. A further option, the SP-100/R enables resistance measurements to be performed
(see Option 6).

Option 1

SCHILLER ECG Measurement Program (M)

CONTENTS

Introduction

The SCHILLER **ECG measurement program** measures the ECG signal and provides the following clearly documented results: heart rate, intervals, electrical axes and detailed measurements for each lead.

This data is the basis for an interpretation with the SCHILLER ECG interpretation program or a diagnosis by the physician.

Results of the ECG Measurement

Heart Rate (HR)

Average heart rate (HR) calculated on the basis of the entire 10 second recording and shown as number of beats per minute.

Intervals

RR: Average time interval between two consecutive ventricular complexes, computed on the basis of the average heart rate.

P: Duration of P wave (interval between markings 1 and 2 of the average ECGs).

PQ: P-Q interval, i.e. period of time between beginning of P wave and beginning of QRS complex (markings 1 and 3 of average ECGs).

QRS: Duration of QRS complex (time interval between markings 3 and 4 of average ECGs).

QT: Interval between beginning of QRS (beginning of ventricular depolarisation) and end of T wave (end of repolarisation phase).

QTC: Normalized QT interval. As the QT interval is dependent on the heart rate, it is often converted into the normalized QTC interval (i.e. the QT the patient would show at a HR of 60/min). Usually, the QTC amounts to 390 ±40 msec.

The conversion is achieved according to the following formula:

$$QTC = QT * \sqrt{\frac{1000}{RR}}$$

Electrical Axes

The electrical axes of the heart are determined separately for the P, T and QRS waves. They indicate the main spreading direction of the electrical vector in the *frontal plane*.

The SCHILLER measurement program calculates the axes on the basis of the maximum deflection of the relevant waves in leads I and aVF. The following formula is used for the calculation:

$$\text{axis a} = \arctan[\max(aVF) / \max(I)]$$

NOTE: *Large discrepancies may be found between two measurements with faint P and T waves. It is also a known that breathing and the position of the patient (recumbent or standing) result in changes of the electrical axes.*

Detailed Measurements for Each Lead

The SCHILLER mesurement program prints a table with lead-specific measurement results.

In 12 columns, i.e. for each standard lead, the amplitude values of the P, Q, R, S, R', S' T, and T' waves, the J point and the ST integral are listed in millivolts (mV).

The amplitude measurements relate to a reference value that correponds to the signal value immediately before the beginning of the QRS complex (marking 3 on the average ECGs).

The duration of the Q, R, S, R' and S' waves is indicated in milliseconds (ms).

The measurements are designated as follows:

P:	amplitude of P wave
Q:	amplitude of Q wave
Qd:	duration of Q wave
R:	amplitude of R wave
Rd:	duration of R wave
S:	amplitude of S wave
Sd:	duration of S wave
R':	amplitude of R' wave
R'd:	duration of R' wave
S':	amplitude of S' wave
S'd:	duration of S' wave
J:	amplitude of J point (marking 4 of average ECGs)
ST:	ST integral: averaged amplitude of ST segment (from J point to half the distance between J-point and T wave maximum)
T:	amplitude of T wave
T':	amplitude of T' wave (in case of a diphasic T wave)

Option 2

SCHILLER ECG Interpretation Program (C)

CONTENTS

Introduction

The SCHILLER ECG Interpretation program was developed in co-operation with leading cardiologists and is designed to assist the physician in reading and evaluating the ECG printout. The interpretation provided by the SCHILLER ECG Interpretation program does not replace a detailed report by the physician; no computerised interpretation is completely reliable and a machine cannot deliver a complete diagnosis on the basis of the ECG alone without a considerable amount of additional information. The comprehensive clinical diagnosis will always be the physician's responsibility and his undeniable privilege.

Before listing the statements, we would like to briefly recall the essential principles of ECG analysis and evaluation.

The ECG evaluation should always be systematic and conducted in a predetermined order. Before each ECG evaluation you should verify whether the recording was done correctly, and whether the patient received any heart-active medication (digitalis, beta-blockers, anti-arrhythmics, diuretics etc.). Clinical findings and diagnosis have to be known to the evaluating person.

The following procedure is recommended for evaluation:

1. Determine rhythm or rhythm disturbances.
2. Determine heart rate.
3. Measure duration of P, PQ, QRS and QT.
4. Systematic examination of P, Q, R, S, T waves and ECG segments (ST segment etc.).
5. Determine electrical axis in extremity leads and evaluate precordial leads (R/S ratio, transitional zone etc.).
6. Brief description of exceptional and abnormal signs within each single section of the waveform.
7. Overall evaluation.

In this procedure, you are optimally supported by the SCHILLER ECG interpretation program. It supplies the necessary measurement data and suggestions for interpretation.

NOTE: *For an efficient evaluation of interpretation statements it is important that the patient data has been entered, especially patient's age and sex as well as any medication.*

Explanation of Interpretation Statements

On the following pages there is an explanation of the possible findings which can result from the interpretation program. Each explanation is accompanied by one of the following general classification statements:

- **Normal ECG**
- **Otherwise normal ECG**
- **Borderline ECG**
- **Possibly abnormal ECG**
- **Abnormal ECG**

Rhythm

Premature atrial contraction(s)

One or several premature beats of the same shape as the predominant beats were detected in the absence of atrial fibrillation.

Bigeminy will appear in addition to this statement if at least three supraventricular extrasystoles are detected, each separated from the preceding one by a single predominant beat.

Trigeminy will appear in addition to this statement if at least three supraventricular extrasystoles are detected, each separated from the preceding one by two predominant beats.

(OTHERWISE NORMAL ECG)

Atrial escape beat(s)

A pause longer than 1.5 times of the predominant R-R interval preceded one or several beats of the same shape as the predominant beats in the absence of atrial fibrillation.

(OTHERWISE NORMAL ECG)

Premature Ventricular contraction(s)

One or several premature beats, differing in shape and size from the predominant beats were detected.

Bigeminy will appear in addition to this statement if at least three ventricular extrasystoles are detected, each separated from the preceding one by a single predominant beat

Trigeminy will appear in addition to this statement if at least three ventricular extrasystoles are detected, each separated from the preceding one by two predominant beats.

(ABNORMAL ECG)

Ventricular escape beat(s)

A pause longer than 1.5 times of the predominant R-R interval preceded one or several beats differing in shape and size from the predominant beats in the absence of atrial fibrillation.

(ABNORMAL ECG)

Beat(s) with aberrant intraventricular conduction

One or several beats were detected differing in shape and size from the predominant beats but occurring in time, i.e. separated from the preceding and following beats by the predominant R-R interval.

(OTHERWISE NORMAL ECG)

Sinus rhythm

A P wave was detected in the averaged ECG cycle, the heart rate ranged from 50 to 100 beats per minute, and the difference in the duration of the R-R intervals between the predominant beats was no greater than 15%.

(NORMAL ECG)

Sinus arrhythmia

A P wave was detected in the averaged ECG cycle, the heart rate ranged from 50 to 100 beats per minute, and the difference in the duration of the R-R intervals between the predominant beats was greater than 15%.

(OTHERWISE NORMAL ECG)

Sinus bradycardia

A P wave was detected in the averaged ECG cycle, and the heart rate was less than 50 beats per minute.

(OTHERWISE NORMAL ECG)

Sinus tachycardia

A P wave was detected in the averaged ECG cycle, and the heart rate was greater than 100 beats per minute.

(OTHERWISE NORMAL ECG)

Supraventricular tachycardia

A P wave was detected in the averaged ECG cycle, and the heart rate was greater than 130 beats per minute.

(OTHERWISE NORMAL ECG)

Nodal rhythm

No P wave was detected in the averaged ECG cycle, the heart rate was less than or equal to 60 beats per minute, the QRS duration of the predominant beats was less than 150ms and the difference in the duration of the R-R intervals between the predominant beats was less than 15%.

(ABNORMAL ECG)

Regular rhythm, no P wave found

No P wave was detected in the averaged ECG cycle, the heart rate was greater than 60 beats per minute, and there was less than 15% difference in the duration of the R-R intervals between the predominant beats.

(POSSIBLY ABNORMAL ECG)

Idioventricular rhythm

No P wave was detected in the averaged ECG cycle and the QRS duration of the predominant beats was greater than 150ms. The heart rate was less than or equal to 40 beats per minute, and there was less than 15% difference in the duration of the R-R intervals between the predominant beats.

(ABNORMAL ECG)

Ventricular tachycardia

No P wave was detected in the averaged ECG cycle and the QRS duration of the predominant beats was greater than 150ms. The heart rate was greater than 150 beats per minute, and there was less than 15% difference in the duration of the R-R intervals between the predominant beats.

(ABNORMAL ECG)

Atrial fibrillation/flutter

No P wave was detected in the averaged ECG cycle, the heart rate was less than 95 beats per minute, and there was at least 15% difference in the duration of at least one R-R interval between the predominant beats.

(ABNORMAL ECG)

Atrial fibrillation with rapid ventricular response

No P wave was detected in the averaged ECG cycle, the heart rate was equal to or greater than 95 beats per minute, and there was at least 15% difference in the duration of at least one R-R interval between the predominant beats.

(ABNORMAL ECG)

Pacemaker spikes noted

More than two typical pacemaker spikes were detected in at least two leads of the original ECG data recorded over 10 seconds.

(ABNORMAL ECG)

Electrical Axis

The electrical axis is computed on the basis of the algebraic sum of the amplitudes and deflections of the QRS complex in leads I and aVF. The possible findings with their corresponding ranges are as follows:

Abnormal left axis deviation	-90°	to	-30°	(ABNORMAL ECG)
Leftward axis	-30°	to	0°	(OTHERWISE NORMAL ECG)
Rightward axis	+90°	to	+110°	(OTHERWISE NORMAL ECG)
Abnormal right axis deviation	+110°	to	+180°	(ABNORMAL ECG)
Abnormal right superior axis deviation	-90°	to	-180°	(ABNORMAL ECG)

Indeterminate axis

The algebraic sum of the deflections of the QRS complex in leads I and aVF ranged between -0.15mV and +0.15mV.

(BORDERLINE ECG)

Atrial Activity

Possible left atrial abnormality

P terminal negative force (maximal negative amplitude of P times terminal negative phase of P) in V1 is -6mVms > P terminal force ≥ -8mVms.

(POSSIBLY ABNORMAL ECG)

Left atrial abnormality

P terminal negative force (maximal negative amplitude of P times terminal negative phase of P) in V1 is -8mVms > P terminal force.

(ABNORMAL ECG)

Right atrial enlargement

For the detection of a right atrial enlargement, points are allocated to different ECG characteristics possibly caused by this condition according to the following criteria:

P-amplitude in II:

1 point if 0.25mV ≤ P amplitude < 0.3mV.
2 points if the P amplitude ≥ 0.3mV.

P-amplitude in III:

1 point if 0.25mV ≤ P amplitude < 0.3mV.
2 points if the P amplitude ≥ 0.3mV.

P-amplitude in aVF:

1 point if 0.25mV ≤ P amplitude < 0.3mV.
2 points if the P -amplitude ≥ 0.3mV.

The test for right atrial enlargement yielded at least three points.

(POSSIBLY ABNORMAL ECG)

Biatrial enlargement

The conditions for (possible) left atrial abnormality and (possible) right atrial enlargement (at least two points in the test) have been satisfied.

(ABNORMAL ECG)

Prolonged P-R interval

The duration of the P-R interval was longer than: $21 \times \sqrt[4]{10 \times \text{R-R interval}} + 10$ [ms] or 220ms, whichever is less.

(ABNORMAL ECG)

ECG Voltages

Low limb lead voltage

The sum of the peak-to-peak QRS amplitudes in leads I, II and III was 1.5mV or less, but one or several peak-to-peak QRS amplitudes in the chest leads was greater than 0.7mV.

(BORDERLINE ECG)

Low voltage

The sum of the peak-to-peak QRS amplitudes in leads I, II and III was 1.5mV or less, and the difference between the maximal QRS amplitudes in V4-V6 and the minimal QRS amplitudes in V1-V3 was 0.7mV or less.

(ABNORMAL ECG)

Blocks

Right bundle branch block

The total duration of QRS was at least 130ms. The R/S ratio in lead V2 was greater than 1, or an S wave deeper than 0.20mV was detected in leads I and V6. In lead V1 or lead V2 a notched QRS complex or a QRS complex of the RSR' type was found.

(ABNORMAL ECG)

Incomplete right bundle branch block

The total duration of QRS was shorter than 130ms. In lead V1 or lead V2 a notched QRS complex or a QRS complex of the RSR' type was detected and the R' wave in one of those two leads had an amplitude of at least 0.15mV.

(OTHERWISE NORMAL ECG)

Left bundle branch block

The total duration of QRS was at least 130ms. The R/S ratio in lead V2 was less than 1. If an S wave was found in leads I and V6, it was not deeper than -0.2mV and the R/S ratio was ≥ 1. The Q wave amplitude in either lead I or lead V6 was ≥ -0.09mV.

(ABNORMAL ECG)

Incomplete left bundle branch block

Same as left bundle branch block, except that the total duration of QRS was shorter than 130ms and longer than or equal to 120ms.

(POSSIBLY ABNORMAL ECG)

Non-specific intraventricular block

The total duration of QRS was at least 130ms. The criteria for left bundle branch block, right bundle branch block, left anterior or left posterior fascicular block were not fulfilled.

(ABNORMAL ECG)

Non-specific intraventricular delay

The total duration of QRS was shorter than 130ms but longer than or equal to 120ms. The criteria for incomplete left bundle branch block, incomplete right bundle branch block, left anterior or left posterior fascicular block were not fulfilled.

(BORDERLINE ECG)

Left anterior fascicular block

No Q wave was present in lead aVF, i.e. the ventricular depolarisation started in a downward direction. The R/S ratio in lead aVF was 0.6 or less, and the electrical axis ranged between -30 and -120 degrees. An S wave with an amplitude of ≤ -0.25mV must be present in lead V6.

(ABNORMAL ECG)

Left posterior fascicular block

The electrical axis ranged between +115° and +180°. The Q wave amplitudes in II, III and aVF were ≤ -0.02mV, and the Q durations in III, aVF were ≤ 40ms. The R or R' amplitude in II was ≥ 0.8mV, and in III ≥ 1.0mV.

(ABNORMAL ECG)

Bifascicular block

A left anterior fascicular block or a left posterior fascicular block occurred together with a right bundle branch block.

(ABNORMAL ECG)

QRS Abnormalities

NOTE: ***CANNOT RULE OUT** is substituted by **CONSIDER** in the following statements if in addition to the QRS contour abnormality pathognomonic inverted T waves were detected in appropriate leads, i.e.*

- II and aVF for inferior localisation
- V1, V2 and V3 for anteroseptal localisation
- V4, V5 and V6 for anterolateral localisation
- I and aVL for lateral localisation

QRS (T) contour abnormality, cannot rule out anteroseptal myocardial damage

There was a pathological start of the ventricular depolarisation. The initial momentary QRS vectors were directed backward and mostly to the left, and remained in this direction during the greater part of the ventricular depolarisation, instead of remaining directed forward for the first 30ms then turning backwards and to the left.

(BORDERLINE ECG)

QRS (T) contour abnormality, cannot rule out anterolateral myocardial damage

The ventricular depolarisation started normally, the initial momentary QRS vectors being directed forward and to the right. However, instead of then turning to the left and backwards, the momentary QRS vectors turned further to the right and backwards.

(BORDERLINE ECG)

QRS (T) contour abnormality, cannot rule out lateral myocardial damage

The ventricular depolarisation started normally, the initial momentary QRS vectors being directed forwards and to the right. However, instead of then turning to the left and backwards, the momentary QRS vectors remained directed forwards and more to the right than normal, i.e. the turn to the left was postponed.

(BORDERLINE ECG)

QRS (T) contour abnormality, cannot rule out inferior myocardial damage

The initial 10 to 20ms momentary QRS vectors were directed upward, which is still normal, but instead of turning immediately downwards, the momentary QRS vectors remained directed upward for at least the first 40ms of the ventricular depolarisation and often remained directed upwards during the greater part of the ventricular depolarisation.

(BORDERLINE ECG)

Myocardial Infarctions

A diagnosis of myocardial infarction requires the detection of at least one pathognomonic Q or QS wave (Q/QS), i.e. a Q-wave which measures at least 25% of the amplitude of the following R wave in leads I, II, aVL, aVF, or V1 to V6.

The ECG interpretation program enables the detection of myocardial infarctions within the following areas:

septal	Q/QS in V2
anteroseptal	Q/QS in V2 and V3, Q/QS in V1 to V3.
anterior	Q/QS in V4, or any combination of Q/QS in V4 with Q/QS in any other precordial lead
anterolateral	Q/QS in V5 or in V5 and V6
lateral	Q/QS in V5 and/or V6 and Q/QS in I and/or aVL
high lateral	Q/QS in I and aVL
inferolateral	Q/QS in II and/or aVF and Q/QS in V6
inferior	Q/QS in II and/or aVF

A diagnosis of myocardial injury will be replaced by a diagnosis of myocardial infarction if a Q/QS was detected in the anteroseptal, anterolateral, anterior or high lateral localisation as defined above. The patient however must be at least 30 years old otherwise INFARCT will be substituted by MYOCARDIAL DAMAGE.

If only one Q/QS was detected in a certain area, the following diagnosis will appear:

QRS (T) contour abnormality, consider ..... infarct

If more than one Q/QS was detected in a certain area, the following diagnosis will appear:

QRS (T) contour abnormality, consistent with ..... infarct

Exception: The septal location is always associated with "cannot rule out".

When a diagnosis of myocardial infarction is proposed, the program endeavours to determine its age:

Probably old will appear if no specific ST and T changes were detected in the leads defining the infarct localisation.

Possibly recent — **will appear if a significant ST elevation was detected in the leads defining the infarct localisation.**

Age undetermined — **will appear in all other cases.**

A diagnosis of myocardial infarction will always have the classification ABNORMAL ECG.

ST-T Morphology

ST abnormality, possible anteroseptal subendocardial injury

ST depressed by at least 0.25mV in at least one of leads V1, V2 and V3, and no QRS signs of an anteroseptal myocardial injury or infarct were detected.

(ABNORMAL ECG)

ST abnormality, possible anterior subendocardial injury

ST depressed by at least 0.25mV in other precordial lead combinations than those typical for anteroseptal and anterolateral injuries, and no QRS signs of an anterior myocardial injury or infarct were detected.

(ABNORMAL ECG)

ST abnormality, possible anterolateral subendocardial injury

ST depressed by at least 0.25mV in at least one of leads V4, V5 and V6, and no QRS signs of myocardial injury or infarct were detected.

(ABNORMAL ECG)

ST abnormality, possible lateral subendocardial injury

ST depressed by at least 0.25mV in leads V5 and V6, and at least 0.1mV in leads I and aVL, and no QRS signs of a lateral myocardial injury or infarct were detected.

(ABNORMAL ECG)

ST abnormality, possible inferior subendocardial injury

ST depressed by at least 0.1mV in leads II and aVF, and no QRS signs of an inferior myocardial injury or infarct were detected.

(ABNORMAL ECG)

Non-specific ST depression

ST depressions other than those mentioned above were detected.

(BORDERLINE ECG)

ST & T abnormality, consider anteroseptal ischemia or right ventricular strain

ST depressed by 0.05 to 0.09mV with T diaphyseal or negative, or ST depressed by 0.10 to 0.24mV with T flat, diaphyseal or negative in at least one of leads V1, V2 and V3, and no QRS signs of an anteroseptal myocardial injury or infarct were detected.

(ABNORMAL ECG)

ST & T abnormality, consider anterior ischemia or left ventricular strain

ST depressed by 0.05 to 0.09mV with T diaphyseal or negative, or ST depressed by 0.10 to 0.24mV with T flat, diaphyseal or negative in other precordial lead combinations than those typical for anteroseptal and anterolateral ischemia or left ventricular strain.

(ABNORMAL ECG)

ST & T abnormality, consider anterolateral ischemia or left ventricular strain

ST depressed by 0.05 to 0.09mV with T diaphyseal or negative, or ST depressed by 0.10 to 0.24mV with T flat, diaphyseal or negative in at least one of leads V4, V5 and V6, and no QRS signs of an anterolateral myocardial injury or infarct were detected.

(ABNORMAL ECG)

ST & T abnormality, consider lateral ischemia or left ventricular strain

ST depressed by 0.05 to 0.09mV with T flat, diaphyseal or negative in at least one of leads I, aVL and V6 and no QRS signs of a lateral myocardial injury or infarct were detected.

(ABNORMAL ECG)

ST & T abnormality, consider inferior ischemia or left ventricular strain

ST depressed by 0.05 to 0.09mV with T flat, diaphyseal or negative in leads II or aVF, and no QRS signs of an inferior myocardial injury or infarct were detected.

(ABNORMAL ECG)

ST & T abnormality, consider recent ..... myocardial or precordial damage

ST elevated at least 0.30mV in at least two V leads or two inferior leads (II, aVF, III) and followed by a flat or negative T-wave, and no QRS signs of a myocardial damage or infarct were detected within the same localisation.

(ABNORMAL ECG)

Non-specific ST-T abnormality (elevation)

An ST elevation of at least 0.2mV was detected accompanied by a T wave in the same lead higher than the normal upper limits as given below in at least two V leads or two arm leads.

(OTHERWISE NORMAL ECG)

T abnormality in anteroseptal leads

T diaphyseal or negative in at least one of leads V2 and V3, and no QRS signs of an anteroseptal myocardial injury or infarct were detected.

(ABNORMAL ECG)

T abnormality in anterior leads

T diaphyseal or negative in other precordial lead combinations than those typical for anteroseptal and anterolateral myocardial injuries was detected.

(ABNORMAL ECG)

T abnormality in anterolateral leads

T diaphyseal or negative in at least one of leads V4, V5 and V6, and no QRS signs of an anterolateral myocardial injury or infarct were detected.

(ABNORMAL ECG)

T abnormality in lateral leads

T diaphyseal or negative in at least one of leads I, aVL and V6, and no QRS signs of a lateral myocardial injury or infarct were detected.

(ABNORMAL ECG)

T abnormality in inferior leads

T diaphyseal or negative in lead II or aVF, and no QRS signs of an inferior myocardial injury or infarct were detected.

(ABNORMAL ECG)

Non-specific T abnormality

T changes other than those mentioned above were detected.

(BORDERLINE ECG)

T-wave table (amplitudes in mV)

		aVL	I	-aVR	II	aVF	III
NORMAL	Upper limit	0.22	0.35	0.34	0.43	0.31	0.22
	Lower limit	-0.05	0.07	0.09	0.08	0.00	-0.12
FLAT	Lower limit	—	-0.04	-0.04	-0.04	-0.04	—
NEGATIVE	Upper limit	-0.06	-0.05	-0.05	-0.05	-0.05	-0.13

		V1	V2	V3	V4	V5	V6
NORMAL	Upper limit	0.39	1.01	1.07	1.04	0.78	0.49
	Lower limit	-0.13	0.17	0.20	0.16	0.13	0.08
FLAT	Lower limit	—	-0.04	-0.04	-0.04	-0.04	-0.04
NEGATIVE	Upper limit	-0.14	-0.05	-0.05	-0.05	-0.05	-0.05

QT Interval

Prolonged QT

A QTc duration longer than or equal to 470ms was detected.

(BORDERLINE ECG)

Hypertrophy

Left ventricular hypertrophy

For the detection of a left ventricular hypertrophy, points are allocated to different ECG characteristics possibly caused by this condition according to the following criteria (modified **Romhilt-Estes** point score):

QRS amplitudes: 3 points if

- the sum of the R-amplitude in lead V5 and the absolute value of the S-amplitude in lead V1 exceeds an age and sex-dependent limit (Sokolow-Lyon). For every 0.5mV above the limit, a further point is attributed.
- the greatest R or S deflection in the extremity leads was equal to or greater than an age and sex-dependent limit (for every 0.3mV above the limit, a further point is attributed.)
- the greatest S deflection in leads V1 to V2 was equal to or greater than an age and sex-dependent limit (for every 0.5mV above the limit, a further point is attributed).
- the greatest R deflection in leads V5 to V6 was equal to or greater than an age and sex-dependent limit (for every 0.5mV above the limit, a further point is attributed).

From the *first* two criteria, the one with the most points is chosen, then from this one and the *last* two criteria the one with the most points is chosen.

ST & T: 3 points if

- an ST depression and a negative or diaphysis T wave were detected in leads I, aVL, aVF, V5 or V6.

  Only 1 point is attributed when the patient is under digitalis medication.

LAA: 3 points if

- left atrial abnormality is present and the amplitude criteria scored at least 3 points.

Electrical axis: 2 points if

- QRS axis ranged from -15 to -120 degrees.

Other QRS criteria: 1 point each if

- the interval between the onset of QRS and the maximum QRS vector was longer than 55ms, and
- the total duration of QRS was longer than 110ms.

No search for LVH is done in the presence of LBBB, RBBB, unspecific intraventricular Block or WPW.

Consider left ventricular hypertrophy

The patient is at least 18 years old and the ECG scored at least 7 points according to the criteria above (3 of these points must stem from the amplitude criteria).

(POSSIBLY ABNORMAL ECG)

Left ventricular hypertrophy

The patient is at least 18 years old and the ECG scored 9 points according to the criteria above (3 of these points must stem from the amplitude criteria).

(ABNORMAL ECG)

Amplitude criteria for left ventricular hypertrophy

The patient is at least 18 years old and of all criteria for left ventricular hypertrophy, only the amplitude criteria were satisfied, and with 6 points.

(POSSIBLY ABNORMAL ECG)

Moderate amplitude criteria for left ventricular hypertrophy

The patient is at least 18 years old, and of all criteria for left ventricular hypertrophy, only the amplitude criteria were satisfied, but only with 3 to 5 points.

(BORDERLINE ECG)

Right ventricular hypertrophy

For the detection of a right ventricular hypertrophy, points are allocated to different ECG characteristics possibly caused by this condition according to the following criteria:

Amplitudes: 3 points if

- the R deflection in lead V1 was greater than an age- and sex-dependent limit and
- the S deflection in the same lead was not deeper than an age and sex-dependent limit (these limits are different in the case of an incomplete or complete RBBB), and
- an S wave deeper than an age and sex-dependent limit was detected in lead V5 or V6, and
- the R/S ratio was less than an age and sex-dependent limit in these leads.

ST & T: 2 points if

- an ST depression and a negative or diphasic T wave were detected in leads V1 to V3. Only 1 point is attributed when the patient is under digitalis medication.

Electrical axis: 2 points if

- The QRS axis ranged from +90 to +180 degrees, or from -120 to -180 degrees.

QRS duration: 1 point if

- the total duration of QRS ranged from 100 to 120ms.

No search for RVH is done in the presence of a WPW or right bundle branch block.

Consider right ventricular hypertrophy

The ECG scored 5 points according to the above criteria or 4 points in the presence of a right atrial hypertrophy or of a sagittal electrical axis (i.e. S1, S2, S3 pattern).

(POSSIBLY ABNORMAL ECG)

Right ventricular hypertrophy

The ECG scored at least 6 points according to the above criteria or 5 points in the presence of a right atrial hypertrophy or of a sagittal electrical axis (i.e. S1, S2, S3 pattern).

(ABNORMAL ECG)

Miscellaneous Statements

S1, S2, S3 pattern

An S-wave of at least 0.2mV was detected in leads I, II and III, and the R/S quotient did not exceed 0.25 in the same leads.

(OTHERWISE NORMAL ECG)

WPW pattern, type A

Δ-waves are detected in at least 3 leads. The QRS area was positive in lead V1.

(ABNORMAL ECG)

Consider WPW, type B

Δ-waves are detected in at least 3 leads. The QRS area was negative in lead V1.

(ABNORMAL ECG)

R-S transition zone in V leads displaced to the right

An R/S quotient of at least 3 was detected in lead V2, and the duration of QRS was not longer than 120ms.

(OTHERWISE NORMAL ECG)

R-S transition zone in V leads displaced to the left

An R/S quotient less than 0.75 was detected in lead V5, and the duration of QRS was not longer than 120ms.

(OTHERWISE NORMAL ECG)

*** Possible reversal of the arm leads**

The QRS complexes in leads I and V6 were more discordant than concordant, and the P-wave in lead I was negative.

Low Sensitivity Statements

When 'LOW' sensitivity is selected, the following statements regarding non-specific ECG findings will be suppressed:

- Indeterminate axis
- Low limb lead voltage
- Non-specific intraventricular delay
- Prolonged QT
- Non-specific ST depression
- Non-specific T abnormality
- Non-specific ST-T abnormality (elevation)
- Cannot rule out myocardial damage
- Moderate amplitude criteria for LVH

If one of the above statements has been suppressed, and no other abnormalities are found, the normal/abnormal classification will be replaced by "No specific ECG abnormalities".

The statement "Atrial fibrillation/flutter" is replaced with "Irregular rhythm, no P-wave found".

Option 3

Frank Vectorcardiography

CONTENTS

Introduction

The CARDIOVIT CS-100 can be equipped with optional software for Frank vectorcardiography which can be a very useful diagnostic tool, especially in the diagnosis of infarction. With this option, a plot of the vector loops (saggital, frontal and horizontal representations) can be produced on the basis of the corrected Frank XYZ leads.

NOTE: *Option 1 (ECG Measurement program M) or option 2 (ECG Interpretation program C) must be installed.*

The loops are plotted as a sequence of segments, each segment representing a time unit of 2.5ms which allows determination of the exact vector position for any point in time within the QRS. The variation in time of the vector is an important factor, especially its position within the first 40ms of QRS activity. For this reason, the positions at 10, 20, 30 and 40ms after the beginning of QRS are clearly marked.

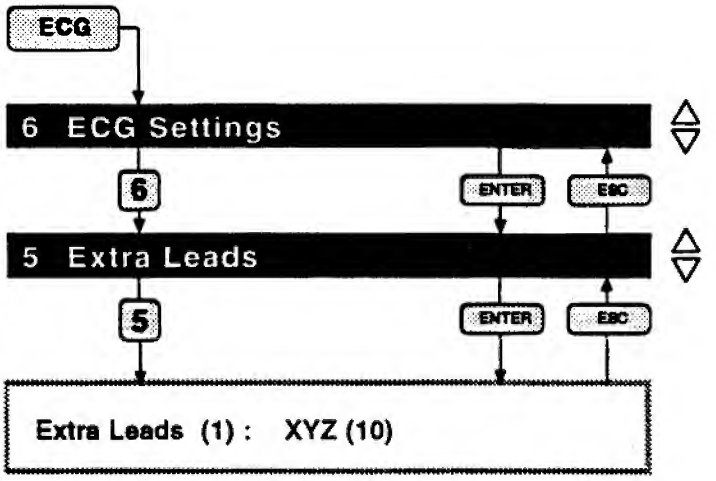
Preparations

Attach Electrodes

Attach the electrodes in the Frank positions (see Chapter 2 "Frank Leads X,Y,Z")

Select Frank Leads

To select the Frank leads, press the following keys:



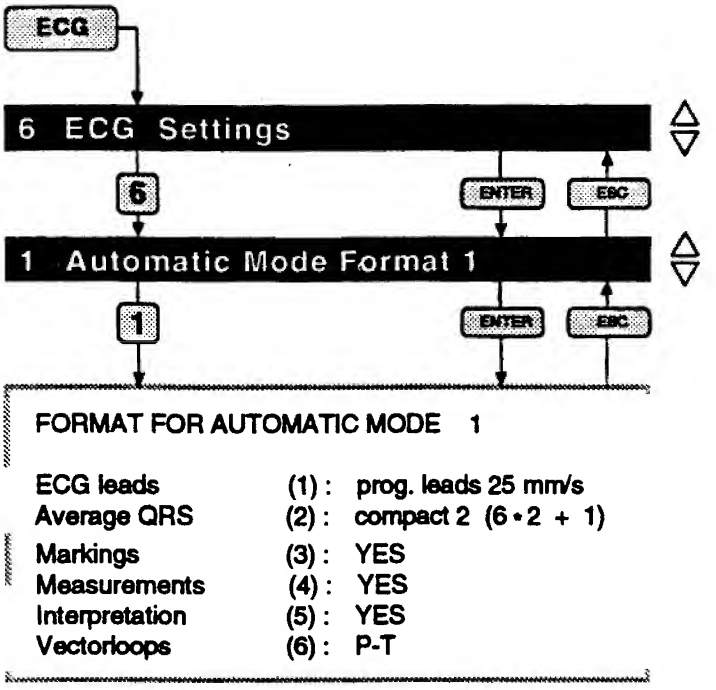
Press key 1 until **"XYZ (10)"** appears for the extra leads. You can also select the uncorrected, orthogonal, bipolar leads for the recording (select "X,Y,Z Bip" in the above menu; for electrode positions see instructions in Chapter 3 "Select Extra Leads").

Now press ESC twice to return to the main ECG menu. Select **"12 Lead /XYZ"** (key 5). The Frank XYZ leads are displayed on the screen.

NOTE: ***The above setting should be selected when working with the 10-lead cable. When the optional 13-lead cable is used, select "XYZ (13)" in the above menu and place electrodes in the appropriate positions (see instruction in Chapter 3 "Select Extra Leads").***

Printout Settings

To select the Vector Loops for the printout, press the following keys:



Press key **6** to select **"Vectorloops"**.

Select between the following formats:

P-T	Vector loops will be plotted from the beginning of P to the end of the T-wave
Q-T	Vector loops will be plotted from the beginning of QRS to the end of the T-wave

NOTE: *Make sure that 'Measurements' is set to YES in the above menu. The other settings in this menu are not active for a printout of the Frank vector loops.*

Printing Out Vector Loops

To initiate a printout of the vector loops, press the **AUTO START** key (the vector loops cannot be printed out in manual mode).

The printout comprises two pages. On the first page, 10 seconds of the X,Y and Z leads are printed out together with the patient data, heart rate, intervals and axes and a detailed table of amplitudes and durations for each lead. At the end of this table, the amplitude relationship between Q and R and between R and S is also given as a percentage for each lead. The final entry gives the sum of the R amplitudes in leads X and Y.

On the second page, an average cycle is given for each of the X,Y Z leads with reference markings at the beginning and end of QRS and at the end of the T-wave. This page also gives the vector loops (sagittal, frontal and horizontal), the patient data as well as the sensitivity in mm/mV for both the average cycles and the vector loops.

Option 4

EXEC III Analysis Program for Exercise ECGs

CONTENTS

Introduction

EXEC III is a special program for the real time recording and evaluation of all the data accumulated during exercise testing. With the help of established signal processing algorithms, EXEC III carries out a complete analysis of the ECG (12 simultaneous leads).

Furthermore, specific parameters such as blood pressure and subjective symptoms are entered, co-ordinated according to time and finally integrated into the final report. Additionally, the EXEC III program contains the facility for providing the physician with a diagnostic statement in relation to the probability of coronary artery disease (CAD).

The main objective of the EXEC III program is to accomplish an accurate evaluation of exercise testing and to document all relevant information clearly and concisely.

Performance of the EXEC III Program

Determination of the Dominant QRS Cycle

EXEC III localizes, measures and classifies each recorded ECG cycle. In order to have an efficient beat classification, precise knowledge of the "normal" QRS type is a prerequisite.

For this purpose, a *learning process* is necessary, which EXEC III carries out immediately after starting an exercise test, i.e. during the "P" or pre-exercise phase. EXEC III informs itself in the first place about the frequency of the occurring QRS patterns. The first five QRS are used for the learning process. From these five complexes a characteristic vector is acquired, which describes the dominant QRS type. This so-called reference vector now serves as a comparison vector for subsequent classification of all the accumulated ECG cycles.

As the shape of the QRS can change continuously during the exercise test, EXEC III adapts the reference vector to the changes. When the QRS changes are abrupt (e.g. at an intermittent bundle branch block) a new learning process is automatically initiated. The duration of the learning process depends on the heart rate. As a rule it lasts for 8 to 12 seconds.

QRS Classification

After concluding the learning process, EXEC III is in a position to process each ECG cycle immediately. With the help of artefact-insensitive measuring algorithms, EXEC III determines a characteristic vector that specifies the QRS complex to be processed and which is structurally identical to the reference vector.

Both these characteristic vectors are then compared via a specific decision logic procedure. Through a suitable combination of the measurement results, taking into consideration the empirically determined tolerance range, EXEC III classifies the measured QRS.

Each QRS is classified for signal processing and for medical criteria. The possible classes and the respective processing are shown in the following tables.

Signal Processing Classes

Class	Description	Processing
1.1	Dominant QRS type without strong distortion	Averaging / Update reference vector / Heart rate calculation
1.2	Dominant QRS type with strong distortion	Heart rate calculation / No averaging
1.3	Non-dominant QRS type	Heart rate calculation / No averaging
1.4	Artefact	No heart rate calculation / No averaging

Medical Classes

Class	Description	Processing
2.1	Normal beat	Rhythm analysis
2.2	Supraventricular extrasystole	Rhythm analysis
2.3	Ventricular extrasystole	Rhythm analysis / VES typisation
2.4	Bundle branch block picture	Rhythm analysis

The classification from the signal processing view, is essential in determining whether or not a beat can be used for averaging.
The classification according to the medical point of view determines which part the QRS complex has to play in the subsequent rhythm analysis.

Construction of the Representative Cycles (Averaging)

The aim of reducing the superfluous information and at the same time increasing the quality of the interpretation is achieved through the computation of representative ECG cycles. The representative cycle (standard cycle) always corresponds to the actual normal cycle.

For the formation of a genuine standard cycle free of artefacts, the established method of beat averaging is provided. This is an efficient method to dispose of artefacts, a method that uses the peculiarities of the ECG signals. On principle one utilizes the characteristics of the ECG as a redundant periodic process. The average complex formed by a multitude of normal beats full of artefacts thus leads to a good approximation of the artefact-free original signal.

EXEC III uses an incremental-averaging-algorithm with base-line correction. This is a method which allows only the recurring parts of the signal to be fed into the result. The average cycle is always up-to-date and available at any time.

Analysis of the ST Segment

On the averaged cycle, the ST analysis occurs every 4 seconds. EXEC III determines the position of the J point with the help of a pattern recognition process (template method). If the J point, in relation to the resting cycle, is higher by 0.1 mV, the system would then classify it as ST elevation. The analysis of the ST segment shape thus becomes superfluous. The same applies for the J amplitudes which differ between 0.1mV and -0.1mV. The ST segment is then classified as unobtrusive.

In the event that the J point differs more than -0.1mV, EXEC III identifies an ST depression and carries out an analysis of the shapes of the ST segment in the first 80 milliseconds. It also determines whether the ST segment in this area is fairly rectilinear. Should this be the case, the slope of the regression line in the first 40 milliseconds serves as a measurement for classification.

The following table shows the ST classifications and their respective criteria:

NOTE: *For the U.S.A., the unit measurement **'mm'** will be used instead of mV.*

Degree	Abbr.	Class	J-amplitude D (mV)	ST shape	Slope (mV/sec)
0	--	unobtrusive	0.1 > J > 0.1		
1	AS	ascending	J < -0.1	rectilinear	s > 1.0
2	SA	slowly ascending	J < -0.1	rectilinear	1.0 > s > 0.1
3	HD	horiz/descending	J < -0.1	rectilinear	0.1 > s
4	CC	concave	J < -0.1	basin-shaped	
5	EL	ST elevation relative to resting ECG	0.1 < J		

Rhythm Analysis

The aim of the rhythm analysis is to provide a qualitative and quantitative statement about the heart rhythm during the course of the test.
The following rhythm disturbances are determined:

Ventricular Extrasystoles (VES)

In order to classify the VES, criteria such as duration and shape of the QRS are drawn upon. At the same time the R-R distance has to be shortened.

VES-Types

Beats classified as VES are transferred to a typification algorithm. Up to 5 VES types are differentiated. A VES type is only recognized as such, when at least two matching QRS complexes are identified.

Frequency of VES

VES are counted and successive VES are identified as chains of two or three. At more than three successive VES, a ventricular tachycardia is determined.

Arrhythmia

Totally irregular R-R distances of normal ventricular complexes are classified as irregular rhythm (absolute arrhythmia).

The following table shows the rhythm disturbances documented by EXEC III:

Degree	Abbr.	Description	Data recorded
0	--	No obvious rhythm disturbance	--
1	ES	Isolated VES	Number/Temporal distribution
2	BI	VES as bituminous	Number/Temporal distribution
3	2R	VES as chains of two	Number/Temporal distribution
4	3R	VES as chains of three	Number/Temporal distribution
5	VT	Ventricular tachycardia	Number/Temporal distribution
6	IR	Irregular rhythm	Time of occurrence

Determination of the Heart Rate

The heart rate is constantly computed from the last eight R-R intervals. A beat is however, only used for calculation of the heart rate if it is recognized as a normal beat (class 1.2) or if it has the same medical classification as the preceding beat (e.g. with ventricular tachycardia).

Interpretation

The summary report supplied by EXEC III will give information about the significance of the test. Apart from information concerning ST abnormalities, the subjective symptoms and causes of interruption are shown.

During the whole of the exercise test, EXEC III stores for each lead the ST data with the highest significance and the corresponding maximal ST amplitude (selectable: J00 to J80, J00 to J80 normalized).

ST changes are classified as significant, when the ST classification of degree 2 (or higher) has occurred at least once in a lead, i.e. an ST depression with slow ascending course is already rated as conspicuous.

CAD Probability

The EXEC III program is equipped with a diagnostic algorithm which provides the physician with a diagnostic statement for patients in whom a diagnosis of coronary artery disease (CAD) is suspected. The CAD probability program is based on the logistic regression analysis technique using both clinical and exercise variables and is designed for use with male as well as female patients without previous myocardial infarction and with a normal resting ECG.

The clinical variables used include age, sex, systolic blood pressure, cigarette smoking, total serum cholesterol (not compulsory) and symptom classification (stratification and definition of symptoms according to the Canadian Cardiovascular Society Classification and the "CASS" registry).

Exercise variables included are heart rate and ST segment amplitude (measured 80ms after J) at rest and at peak exercise.

Calculated probabilities vary between 1 and 99%.

NOTE : *This option is not available in the U.S.A .*

ST - HR Trend Plots

The ST - HR trend plots give a graphical representation of the relationship between the ST variation and the heart rate variation, providing a fairly accurate indication of the seriousness of coronary vascular disease. At the end of every exercise stage, a cross is made on the diagram marking the ST position and the heart rate at that moment.

With increased heart rate, patients with a coronary vascular disease will show an increasing ST depression. There is a trend plot for each lead and these 12 diagrams provide an instant overall view of the changes.

The diagrams are accompanied by a measurement table giving the exact figures in micro Volt x minutes. A measured value is only achieved when all the following conditions are satisfied:

- The ST amplitude is under zero.
- The ST distance drops between measurements.
- The heart rate increases.

The following figures are calculated and given on the table:

- ST - HR slope 1: Slope between last and second last measurement
- ST - HR slope 2: Slope between last and third last measurement
- ST - HR slope 3: Slope between last and fourth last measurement
- dHR: As a reference value, the third heart rate change between the above measurement points is given in beats per minute
- I - V6: Summary of all elevations for all 12 leads
- V1 - V6: Summary of all elevations for the chest leads

*NOTE: For the U.S.A., the unit measurement **mm** will be used instead of mV.*

Working with EXEC III

The EXEC III program option does not have to be selected as each time you call up exercise testing and this option is installed, EXEC III is operational. EXEC III can be used for exercise testing with either a bicycle ergometer or a treadmill.

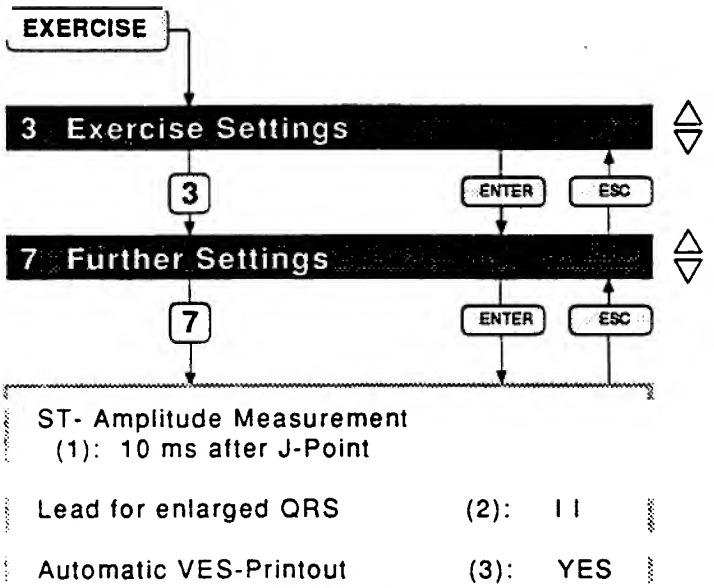
The settings and adjustments for the exercise test are as described in Chapter 5 , however with EXEC III installed, there are several additional functions, such as

- CAD Probability
- selection of a lead for display of an enlarged QRS
- extented final report format

ST Measurement

During an exercise test the ST amplitude is regularly measured. The position of the amplitude measurement point in the ST segment can be freely defined.

Press the following keys:



With keys " - " (decrease) and " + " (increase), the position of the amplitude measurement point within the ST segment is determined. The given temporal distance is measured from the beginning of the ST segment, i.e. the J point. The measurement point can thus be set to either 00, 10, 20, 30, 40, 50, 60, 70 or 80ms after the J point.

Select Lead for Enlarged QRS Complex

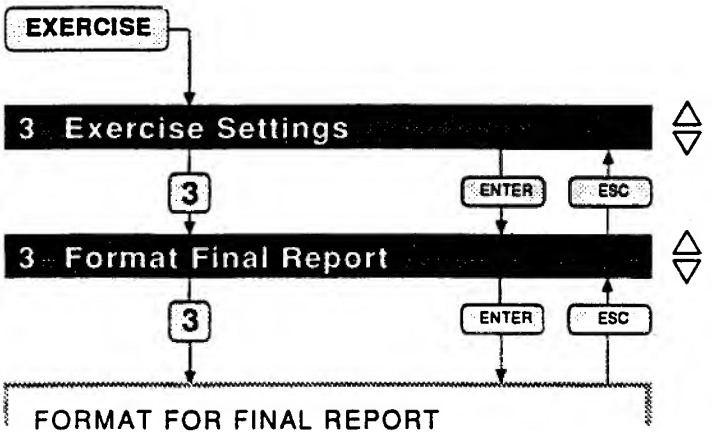
When the exercise test is started, an enlarged QRS is displayed on the right-hand side of the screen. In the above menu, the lead for this enlarged QRS presentation can be selected. Press key **2** and select the desired lead with the + or – key .

Automatic VES Printout

An automatic printout on detection of ventricular extrasystoles (VES) can be initiated (YES) or suppressed (NO) by pressing the key **3**. When switching the unit on, the printout is always activated. If a printout is not required, set to NO.

Define Format for Final Report

To define the format for the final report, press the following keys:



By pressing the number indicated in parenthesis following selections can be made:

ST Trends

- **ST-Trends** **(1):** Select between: YES or NO

  If set to **YES**, the ST trend diagrams are printed out on the second page of the final report. The ST trend diagrams have a time axis of either 30 or 60 minutes depending on the duration of the exercise test.

  The trend diagrams are printed for each lead and show the ST amplitude as a solid line and the ST slope as a dotted line. The ST amplitude measurement point and the unit values for both amplitude (mV) and slope (mV/s) are given at the top of the page.

  The amplitude measurement at the beginning of the ST segment is determined by the user-defined measurement point (see "ST Measurement").

NOTE: *For the U.S.A., the amplitude values will be given in **mm** instead of mV.*

ST-HR Diagrams

- **ST-HR Diagrams** **(2):** Select between: YES or NO

  When set to **YES**, the ST-HR trend plots are printed out on the third page of the final report.

  They give a graphical representation of the relationship between the ST variation and the heart rate variation.

ST Segment Interpretation

- **Interpretation** **(3):** Select between: ST
  Rhy
  ST + Rhy
  NO

  When set to **ST**, the ST segment interpretations are printed out on the first page of the final report. When set to **Rhy**, the rhythm statements will be printed out and when set to **ST + Rhy**, ST and rhythm statements will appear.

Average Cycles

- **Average Cycles** **(4):** Select between: COMPACT
  ALL
  NO

  When set to **COMPACT** or **ALL**, the average cycles are printed out on the fourth and fifth pages of the final report.

  In the COMPACT format, the average cycles are printed in four columns representing from left to right:
  – pre-test phase
  – maximum load
  – start of the resting phase
  – end of resting phase

  When ALL is selected, the average cycles are printed for each stage of the exercise test together with duration and the maximum heart rate achieved.

- **Speed** **(5):** Select between: 25mm/s
  50mm/s

  The chart speed for the average cycles can be set to either 20 or 50mm/s.

- **Channels** **(6):** Select between: 6
  12

  The number of channels on one page can be set to 6 or 12.

Rhythm Leads

- **Rhythm** **(7):** Select between: YES or NO

  When **YES** is selected, rhythm lead R1 will be printed out in the final report (for instructions on how to define this lead, see Chapter 3 "Select Rhythm Leads").

  If a rhythm printout is only desired in the case of rhythm disturbances, select NO. The rhythm lead R1 can be printed at the end of the test, after the final report has been printed out, by pressing the **PRINT RHYTHM** key.

- **Speed** **(8):** Select between: 6.25mm/s
  12.5mm/s

  The speed for the printout of lead R1 can be set to either 6.25 or 12.5mm/s.

- **Sensitivity** **(9):** Select between: NORMAL
  HALF

  The sensitivity of the rhythm recording can be set to either 10mm/mV (NORMAL) or 5mm/mV (HALF).

VES Summary

- **VES Summary** **(0):** Select between: YES or NO

  When set to **YES**, the VES summary is printed out at the end of the final report and provides a summary of all detected ventricular extrasystoles.

Define Coronary Artery Disease (CAD) Probability

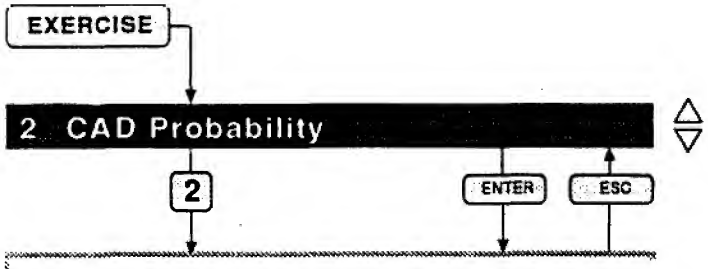
NOTE: *This option is not available in the U.S.A.*

With this function of the EXEC III program, the probability of coronary artery disease (CAD) can be determined.

IMPORTANT: *Following requirements must be fulfilled:*
- *the patient's date of birth must be known (refer to Chapter 3, "Enter the Patient Data")*
- *the patient's age, calculated from his date of birth, is between 26 and 69 years.*

Input of Data

To access the menu for the input of data for CAD probability, press the following keys:



CAD Probability

Cigarette smoking	(1):	NO
Cholesterol	(2):	– – – mmol/ l
Chest pain	(3):	non spec.
AP during exercise	(4):	NO
dST/dHR in V5:		3.1 uV*min
pCAD pretest		? %
pCAD post test		? %

By pressing the number indicated in parenthesis following selections can be made:

- **Cigarette smoking** **(1):** Select between: YES or NO

  With **YES** the patient is identified as a smoker.

- **Cholesterol** **(2):** Select between: ---
  < 6
  6 – 8
  > 8

  The choices available are (---), i.e. there is no known value, **< 6** (the value is less than 6mmol/l), **6 – 8** (the value ranges between 6 and 8mmol/l) or **> 8** (the value exceeds 8mmol/l).

- **Chest pain** **(3):** Select between: non specific
  atypical
  moderate
  severe

- **AP during exercise** **(4):** Select between: YES or NO

  With **YES** you confirm that the patient experienced angina pectoris during exercise testing.

From the data entered, the CAD probability before and after the exercise test is calculated and displayed (pCAD pretest, pCAD post test).

Displayed Values

ST/HR Difference (dST/dHR)

The ST/HR difference measured in lead V5 is given in µV*min.

This value is the difference between the ST amplitude at rest and at peak exercise, divided by the difference between the heart rate at rest and at peak exercise.

CAD Probability Before the Test (pCAD pretest)

This value gives the CAD probability in percentages before the test.

CAD Probability After the Test (pCAD post test)

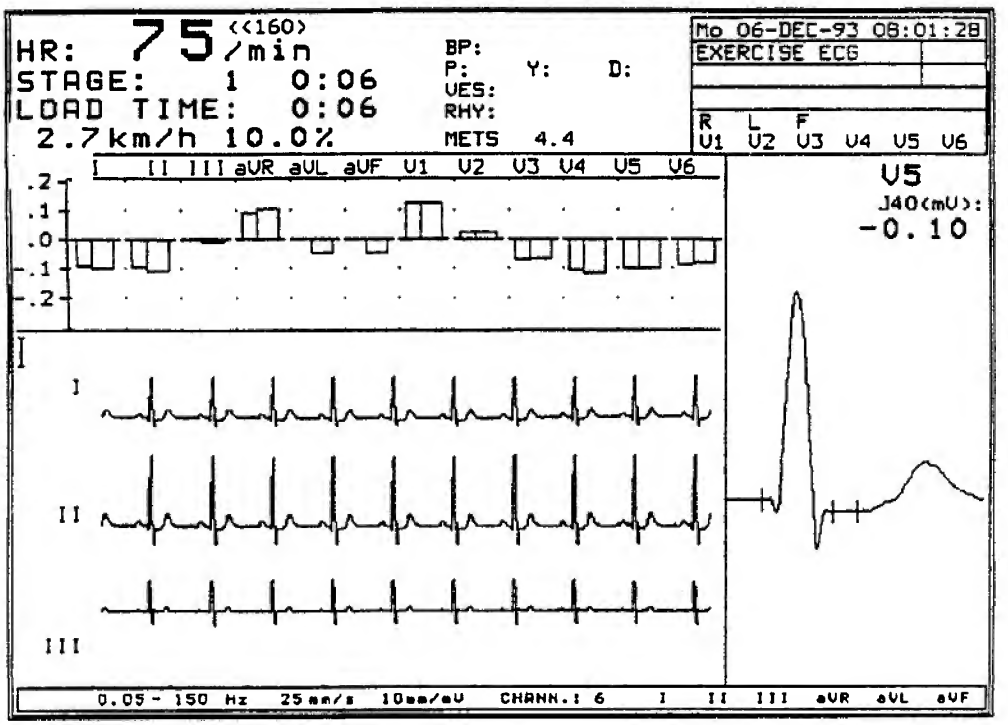
This value gives the CAD probability in percentages after the test (taking into account the dST/dHR value).

Screen Presentations

With the EXEC III program, five screen presentations can be displayed one after the other.

Standard Presentation of Exercise Test

The first presentation which is automatically displayed appears as in the following example:



Top section of display

On the left-hand side, following information is given:

- heart rate with heart rate limit in parenthesis
- stage identification and duration
  P = pre-exercise phase
  1...9 = stage number
  R = recovery phase
- total load time (without pre-exercise phase)
- actual load (bicycle) or speed and grade (treadmill)

This information is continuously updated.

The top central section contains following information:

- actual blood pressure
- manually entered symptoms
- number of detected ventricular extrasystoles
- rhythm classification (ventricular tachycardia, bigeminus or irregular)
  (For tests with a treadmill, the current METS value is also given here.)

All this information is permanently displayed regardless of the selected presentation.

Central section of display

Below the permanently displayed information is a diagrammatic representation of the ST amplitudes for each of the 12 leads.

The block showing the ST amplitude for each lead is divided into two parts.

- The part on the left is for reference purposes and represents the last ST amplitude recorded during the pre-exercise phase.
- The part on the right represents the actual ST amplitude and is continually renewed.

Lower section of display

Below the ST amplitude diagram are three freely selectable leads.

Right-hand side of display

This section shows the enlarged QRS for the selected lead which is continually renewed (see "Select Lead for Enlarged QRS Complex" in this chapter).

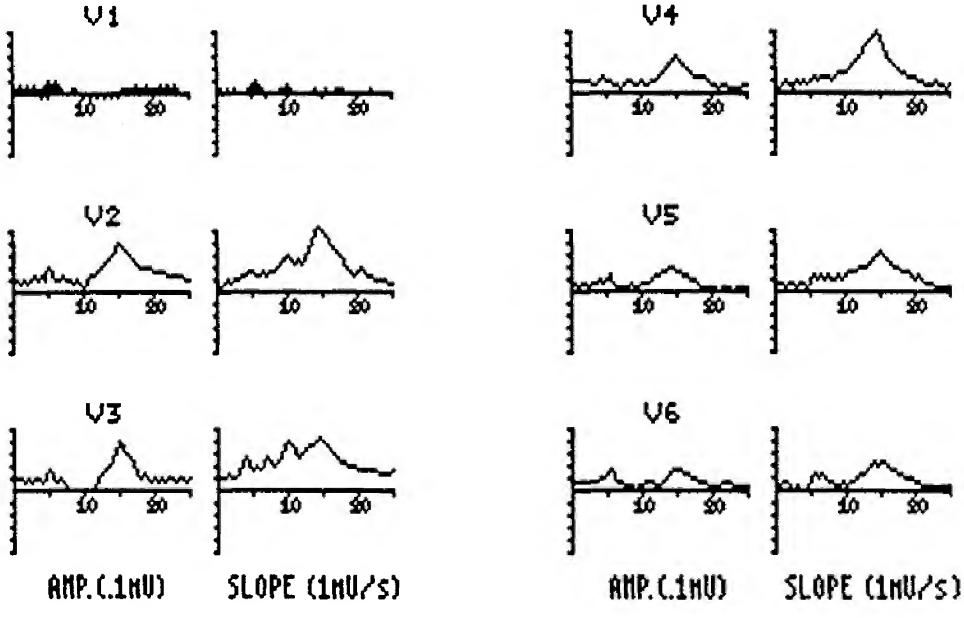
Change Screen Presentation

To change the screen presentation, press the **CHANGE SCREEN** key.

The following displays appear :

- trend plots for blood pressure, load (or speed and elevation) and heart rate
- detailed summary of the occurrences in the extremity leads (ST amplitude trend, ST slope trend)
- summary for the chest leads (see illustration below)
- average cycles for each of the 12 leads
- standard presentation of exercise test

Display of Chest Leads



Option 5

Pacemaker Measurements

CONTENTS

Introduction

The ECG unit detects pacemaker signals which are indicated on the display and on the printout as artificial vertical spikes. With this software option, the characteristics of a pacemaker can be checked and measured. Both single and dual-chamber pacemaker measurements can be made.

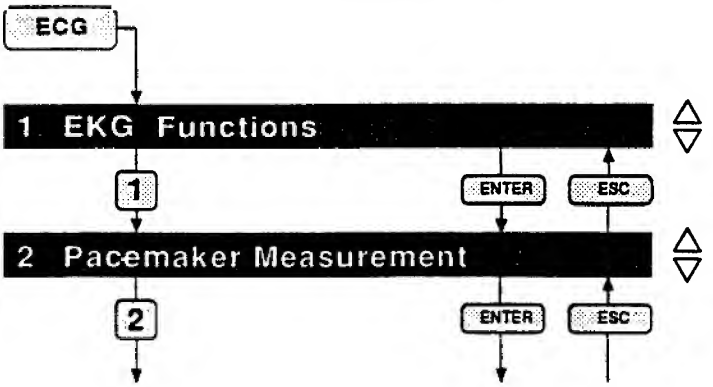
The pacemaker performance is measured between the right arm and the left leg extremity leads.

NOTE: *When carrying out pacemaker measurements, there is a higher risk of electrical interferences. Beware of misinterpretation due to interfering signals!*

Pacemaker Measurement

Activate/deactivate Measurement

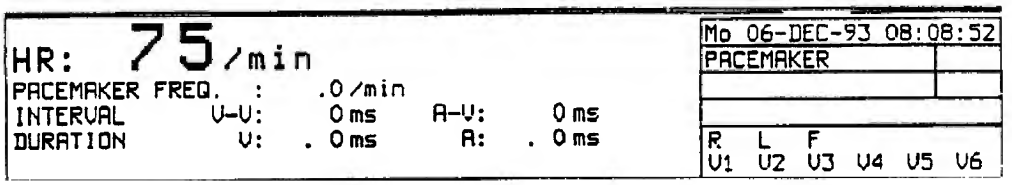
To activate the pacemaker measurements, press the following keys:



By pressing key **2**, pacemaker measurement is activated. Press key **2nd** and **ECG** to deactivate this function.

Displayed Information

When pacemaker measurement is selected, the following information is displayed at the top of the screen:



In the status field at the top right-hand side of the screen, the message "PACEMAKER" indicates that the pacemaker measurement function is active.

The measurements made are displayed in two columns. In the left-hand column the number of stimulations per minute (Pacemaker frequency), the time interval between two stimulations (V-V) and the duration of each stimulation (V) are constantly monitored and updated.

If a dual-chamber pacemaker is being measured, then, in the right-hand column, the time interval between atrium and ventricle stimulations (A-V) and the duration of the atrium stimulation (A) are also given.

Erase Displayed Information

The pacemaker measurements can be removed from the screen by pressing key **2nd** and **ECG**. Otherwise they will remain displayed.

Print Options

To obtain a printout of the pacemaker measurements as displayed on the screen, press the **PRINT SCREEN** key.

As with manual ECG recording, a continous printout with the pacemaker signals can be obtained by pressing the **MAN START** key. The measurement details, however, are not included. To stop the continous printout, press the **STOP** key.

NOTE: *Automatic printing is not possible.*

Option 6

Pulmonary Function Testing

CONTENTS

Introduction

The SPIROVIT SP-110 is a pulmonary function testing option integrated into the CARDIOVIT unit. There are 4 modes for the measurement and calculation of inspiratory and expiratory values and a visual representation of all tests is provided as well as clearly documented test results.

The SPIROVIT SP-110 is simple to operate with easy to follow menu guidance using the normal unit keyboard for data input and test selection. The operating panel of the CARDIOVIT unit provides easy initiation of tests and printouts.

The open pneumotacho sensor is used with disposable mouthpieces and is easily dismantled for cleaning and sterilisation therefore minimizing the possibility of cross-infection.

Preparations for Pulmonary Function Tests

Connect the Flow Sensor

The flow sensor is supplied complete with connecting cable and D sub-miniature connection plug.

Insert the plug into the socket marked "SP-110/R" on the unit and tighten the two securing screws.

NOTE: *The connecting cable should not be exposed to excessive mechanical stress. Whenever disconnecting the cable, hold the plug and not the cable.*

CAUTION: *The flow sensor SP-110 contains a sensitive measuring device and must always be handled with care and not be dropped or subjected to any sudden blows.*

Enter Patient Data

Each ECG is printed out complete with the name and other information concerning the patient. Before beginning an ECG recording, the patient data should be entered.

Press the **PATIENT DATA** key in order to call up the menu for patient data input as follows:

Pat. Name:	Patient name (max. 22 characters)
Pat. No.:	Patient number (max. 22 characters)
Born:	The date of birth has to be entered in figures in the order "day.month.year" separating each with a full stop. For example, for 3rd November 1936, enter "3.11.36" or "03.11.36"
Age:	The age is calculated by the unit on the basis of the date of birth. up to 2 years: Number of months up to 6 years: Number of years and months over 6 years: Number of years
Sex:	(max. 22 characters, only 1 character necessary: M/F)
Height:	Height in centimetres (or in inches for the USA) (max. 3 digits)
Weight:	Weight in kilogrammes (or in pounds for the USA) (max. 3 digits)
BP:	Blood pressure in mmHg (7 digits) systolic/diastolic: *sss/ddd* or *sss.ddd*
Med:	Medication (max. 16 characters)
(rem)	Line for remarks (max. 22 characters)

Terminate each entry with **ENTER**.

Wrongly typed characters can be deleted with the **DELETE** key. Whole lines are deleted as soon as a character is entered at the first position.

NOTE: *If a new patient name is entered, all the other patient data are automatically deleted. After switching off the unit, all patient data remain stored in case an ECG has been recorded.*

Select the Pulmonary Function Test

To enter the pulmonary testing mode, the unit must be in the monitoring mode. By pressing the SPIRO key, the pulmonary testing mode is entered and the main menu is displayed.

On the left side of the screen each step to perform the pulmonary test is shortly explained.

The right side of the screen shows the menu with the pulmonary functions.

Execution of Pulmonary Function Tests

All Pulmonary Function Tests, i.e.

- Forced Vital Capacity (FVC)
- Slow Vital Capacity (SVC)
- Expired or Minute Ventilation (MV)
- Maximum Voluntary Ventilation (MVV)
- Resistance

run in a similar way, so that the instructions are valid for all teats. Exceptions are given at the relevant position.

Display Presentation

The display indicates the measurements which will be made and gives the predicted results. There are three positions for measurement results enabling several tests to be made.

The coordinates represent the graph on which the curve will be drawn with the respiratory volume in litres being represented on the vertical axes for FVC and SVC tests (the relative respiratory volume in litres for **MV** and **MVV** tests) and the time in seconds on the horizontal axis.

Start Tests

NOTE: *The flow sensor must be held quite still and no air should be breathed into the device for at least one second before the AUTO START key is pressed.*

Press the green **AUTO START** key to start the test.

The message "READY FOR MEASUREMENT" appears on the display. As soon as the patient starts to breathe into the flow sensor, the unit begins to record the expiratory flow and the corresponding curve is represented on the display. An acoustic "beep" indicates when the break-off point for the expiration measurement has been reached. Five seconds afterwards, measurement will be automatically interrupted unless the patient inhales thus initiating the inspiration measurement. Expiration or combined expiration/inspiration measurements will still take place should this break-off point not be reached.

Once the test is completed, the measurement results are calculated and given on the display. When subsequent tests are made, the result with the highest FVC + FEV_1 value will always be saved and given in the right-hand column (MEAS 1).

The result with the lowest FVC + FEV_1 value of the tests already made and stored will be overwritten. An asterisk ("*") indicates the measurement results of the last test made.

Interrupt Tests

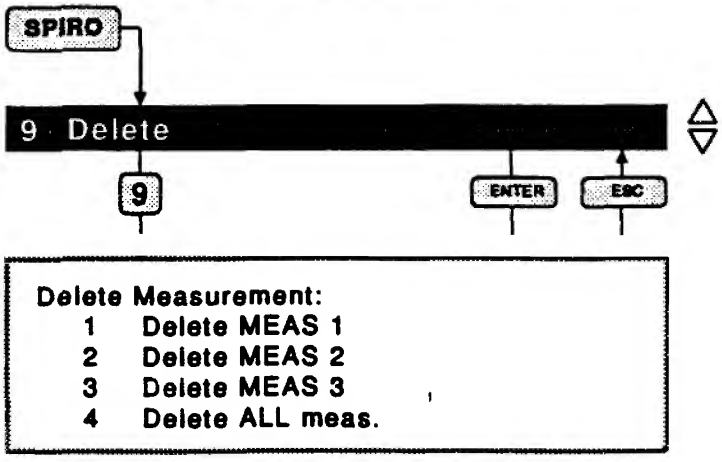
Any of the following pulmonary function tests can be interrupted at any time by pressing the **STOP** key.

Delete Measurements

The display for each test mode has three positions for measurement results, enabling several tests to be made.

When more than three tests are carried out, the result with the best value will always be given in column 1. The result with the lowest value will be overwritten. The last test made is indicated with an asterisk.

Should you require to delete one of the result columns, press FNCT to call up the main menu and then select the following keys:

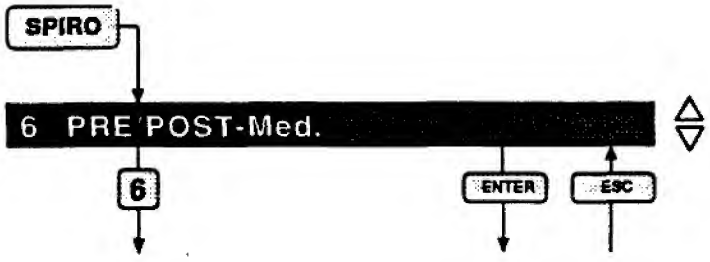


To select a particular column for deletion, press the number of that column (i.e. 1, 2 or 3) and that column will be deleted. If you require to delete all the results, i.e. all three columns, then press **4**.

Select Pre-/Post Medication

Each time the Pulmonary Function Testing program is called up, the unit assumes that Pre-medication tests are to be carried out. This is confirmed by "PRE" which appears in the top left-hand corner of the screen.

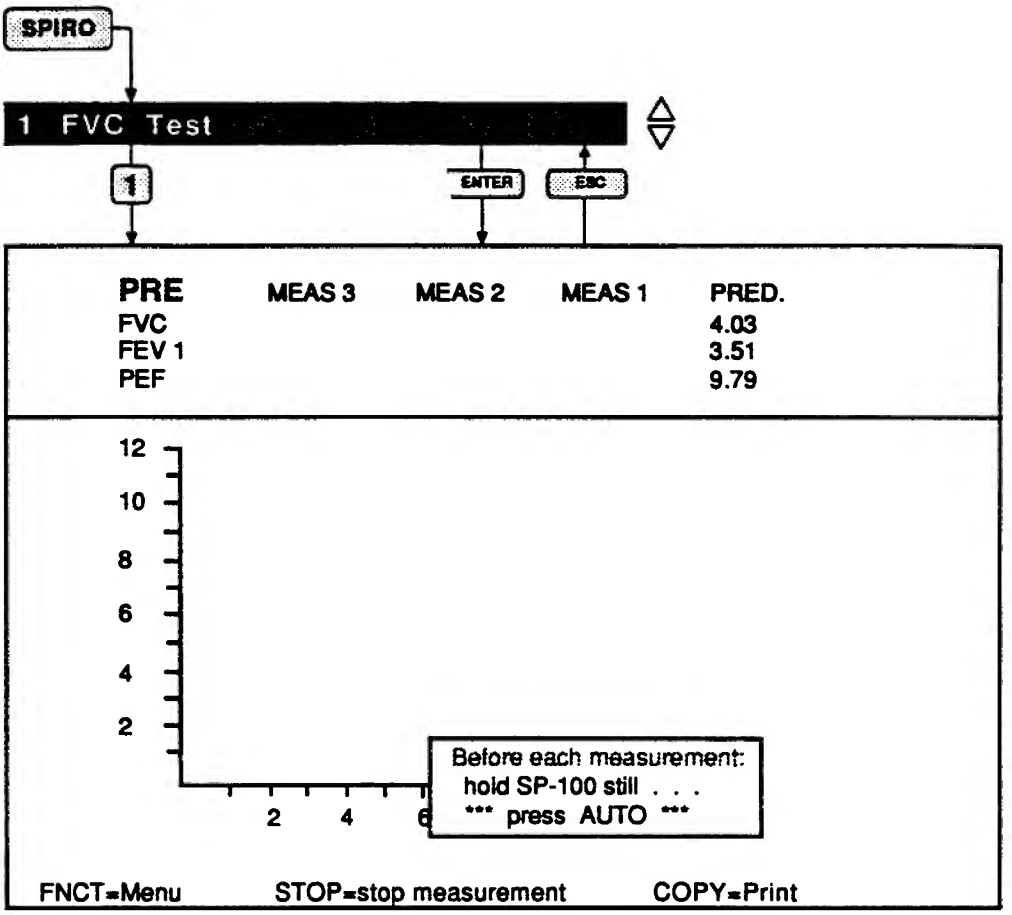
In order to carry out post-medication comparison tests, simply select "PRE/POST Med." when in the main menu and "POST" appears in the top left-hand corner by pressing the following keys:



Each press of the number or ENTER key changes the display between PRE and POST.

Forced Vital Capacity (FVC) Test

To carry out the test for the Forced Vital Capacity (FVC), press the following keys:



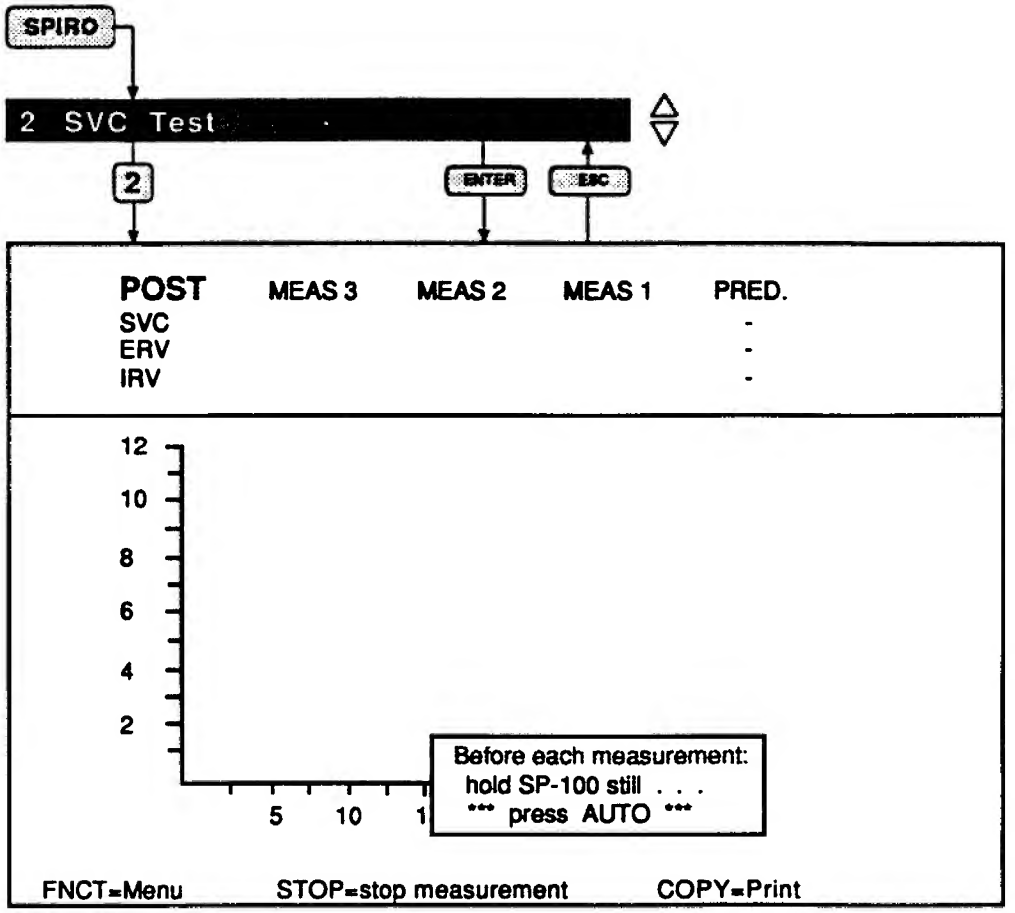
IMPORTANT: *For this test the patient must exhale as quickly as possible from the time of starting the test so be sure that he understands what is required of him.*

If inspiratory measurements are required, the exhalation can be immediately followed by an inhalation. The inspiration results will be given on the printout.

NOTE: *The FVC test employs the 'Back extrapolation' method. If the extrapolated volume is too large (>0.1litres or 10% of FVC), then a warning appears on the display and a question mark (?) will appear in the FEV_1 position for that test.*

Slow Vital Capacity (SVC) Test

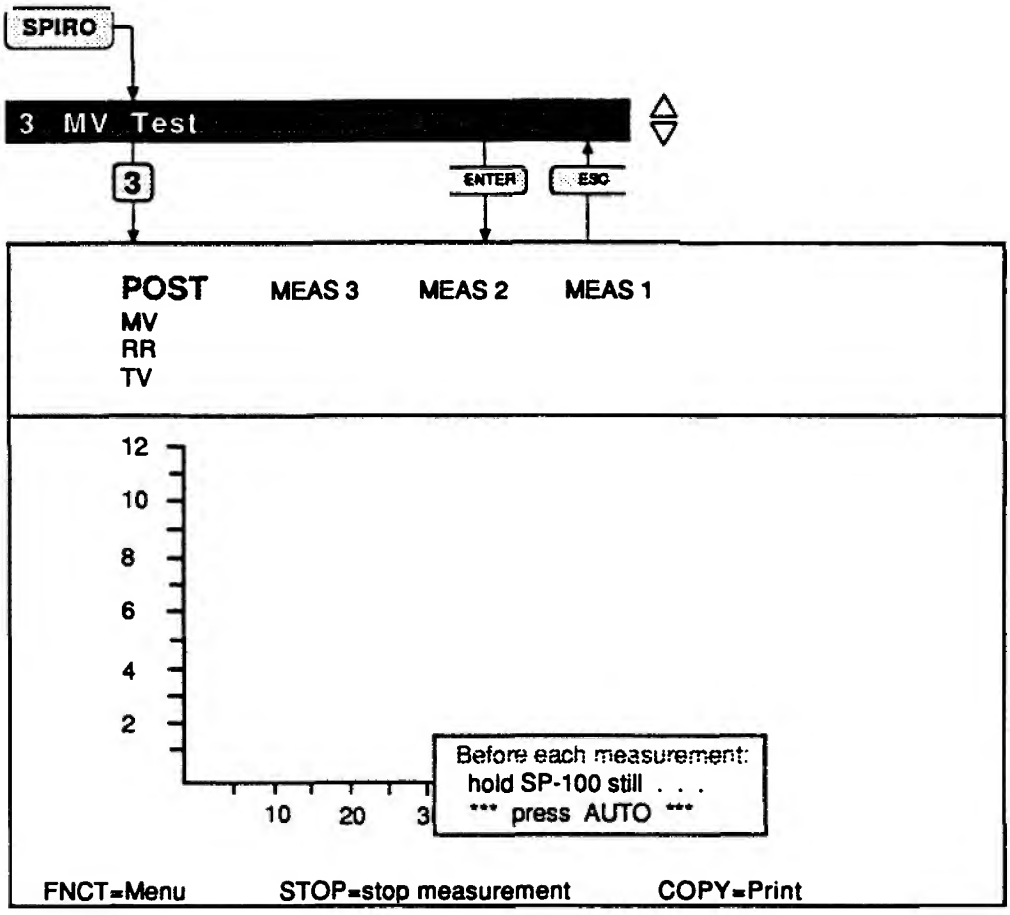
To carry out the test for the Slow Vital Capacity (SVC), press the following keys:



IMPORTANT: *For this test the patient should breathe normally 3 times and then inhale maximally to total lung capacity and then expire maximally. Make sure that the patient understands what is required of him.*

Expired or Minute Ventilation (MV) Test

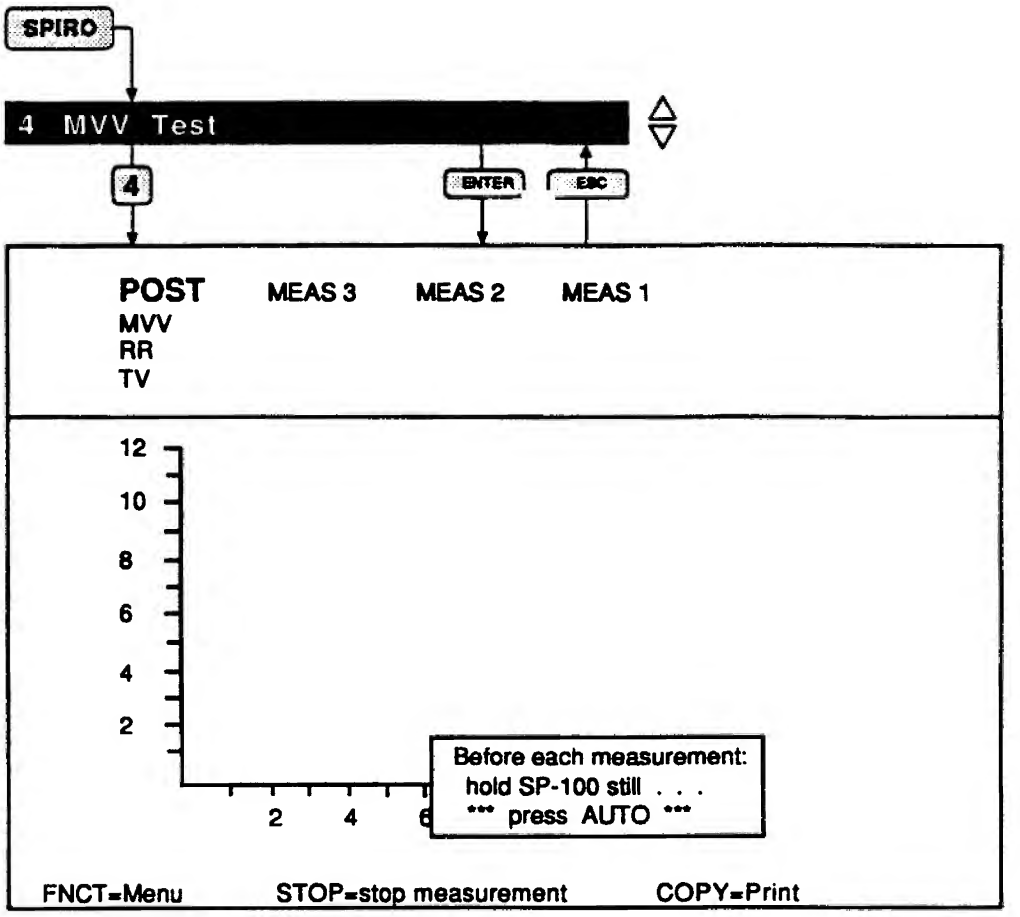
To carry out the test for Expired or Minute Ventilation (MV), press the following keys:



IMPORTANT: For this test the patient should breathe as normally as possible for up to 60 seconds, but for at least 20 seconds. Make sure that the patient understands what is required of him.

Maximum Voluntary Ventilation (MVV) Test

To carry out the test for Maximum Voluntary Ventilation (MVV), press the following keys:



IMPORTANT: *For this test the patient should breathe as deeply and as rapidly as possible over a period of 6 to 12 seconds so make sure that he understands what is required of him.*

WARNING: ***Extreme care should be exercised when performing this test as there is a danger of hyperventilation.***

Printing Out Measurement Results

Print Test Results

A printout can be made for each test by pressing the **COPY** key and the following is superimposed on the display:

```
Print measurement:
   1   best
   2   all
```

To print out only the best measurement of those made and recorded, press **1**. To print out all three measurement results, press **2**.

The patient data, the time and date and the standard used for calculation are printed out for every test but the type of curve and test results will depend on the type of test.

A printout can be interrupted at any time by pressing **STOP**.

Printed Informations with FVC Test

The printout following an FVC test contains the following informations:

- FVC curve as shown on the display (expiratory volume as a function of time)
- The flow curve (flow as a function of the respiration volume)
- The measurement results for FVC, FEV, FEF, PEF, and MEF given as actual, predicted (where available), and actual as a percentage of predicted
- The diagnosis (as indication)

Where an inspiration test has also been carried out, the following results are also given:

- FIVC, FIV, PIF and MIF

Printed Informations with SVC Test

The printout following an SVC test contains the following informations:

- SVC curve as shown on the display (respiratory volume as a function of time)
- The measurement results for SVC, ERV, IRV and TV
- The predicted SVC value
- The actual SVC value as a percentage of the predicted.

If both FVC and SVC tests have been made, then the results from both tests will be included on the same printout.

Printed Informations with MV Test

The printout following an MV test contains the following informations:

- MV curve as shown on the display
- The measurement results for MV, RR and TV

Printed Informations with MVV Test

The printout following an MVV test contains the following informations:

- MVV curve as shown on the display
- The measurement results for MV, RR and TV

If both MV and MVV tests have been made, then the results from both tests will be included on the same printout.

Printed Informations with Post-medication Test

The printout following a post-medication test contains the following informations:

- Curves of both pre and post-medication tests (the pre-medication curve is bold).
- The measurement results are shown as the actual results, actual results as a percentage of those predicted, and the percentage change (i.e. difference) from pre to post-medication results.
- The diagnosis resulting from the pre-medication test is also given on this printout.

NOTE: *The pre-medication results used for the comparison printout are those with the highest values, and not necessarily the last made.*

Abbreviations of Pulmonary Measurement

FVC **Forced vital capacity**
The expiration volume achieved by the quickest possible exhalation after a maximal inhalation.

$FEV_{0.5/1.0/3.0}$ **Forced expiratory volume**
The lung volume in litres, measured after 0.5, 1.0 or 3 seconds of forced expiration.

FEF **Forced Expiratory Flow**
The respiratory flow in terms of differing lung volumes measured in litres per second.

$FEF_{25-75\%/75-85\%}$ Flow speed of the expired air by X% of the forced vital capacity (FVC)

$FEF_{0.2-1.2}$ The averaged flow between 0.2 and 1.2 litres of the forced expired vital capacity.

PEF **Peak Expiratory Flow**

MEF **Maximum Expiratory Flow**

ERV **Expiratory Reserve Volume**
The possible further expiration starting from the normal expiration level.

IRV **Inspiratory Reserve Volume**
The possible further inspiration starting from the normal inspiration level.

TV **Tidal Volume**
The expirational and inspirational volumes during normal respiration.

SVC **Slow Vital Capacity**
The lung volume measured from a complete expiration following a deep inspiration.

MV **Expired or Minute Ventilation**
The volume of expired air in litres per minute measured over a minimum of one minute.

MVV **Maximum Voluntary Ventilation**
The maximum volume of air which can be moved on expiration while breathing as deeply and as rapidly as possible.

RR **Respiration Rate**

FIVC **Forced Inspiratory Vital Capacity**
The inspiration volume achieved between a maximal expiration and a maximal inspiration.

$FIV_{1.0}$ The forced inspiratory air volume in litres measured in the first second.

$FIV_{1.0}$ / FIVC The forced inspiratory air volume measured in the first second as a percentage of forced inspiratory vital capacity.

$FIV_{1.0}$ / FVC The forced inspiratory air volume measured in the first second as a percentage of forced expiratory vital capacity.

PIF **Peak Inspiratory Flow**
The maximum inspiratory flow speed in litres per second.

$MIF_{50\%}$ Flow speed by 50% of the forced inspiratory vital capacity.

Diagnosis and Standards

The diagnostic interpretation and the standards used as a basis for the calculation of predicted values is dependent upon the country. For Great Britain, Italy, Spain, Germany and Switzerland, the ECCS and Quanjer standards are used. For Austria the Austrian, for Sweden the Swedish (Berglund) and Quanjer, and in Finland the Finnish and Quanjer.

In India the Indian standards are used and in America the standards used are Knudson, Crapo, Morris and Composite. The American standards are extended with normals taken from the ITS (Intermountain Thoracic Society).

The factors used in the evaluation for diagnosis and the specific standards are automatically included in the respective language software and described below.

Diagnosis for Countries Outside the USA

Possible respiratory problems are diagnosed on evaluation of the following factors:

	%VC	FEV1%
Normal	>80%	>70%
Restrictive	<80%	-
Obstructive	-	<70%
Combined	<80%	<70%

Restrictive Ventilatory Defect is indicated if:

$$\frac{\text{SVC (or FVC)}}{\text{Predicted SVC}} \times 100\% \text{ is smaller than } 80\%.$$

Obstructive Ventilatory Defect is indicated if:

$$\frac{\text{FEV1}}{\text{SVC}} \times 100\% \text{ is smaller than } 70\%.$$

If both conditions are satisfied, a combined Obstructive/Restrictive Ventilatory Defect is indicated.

Diagnosis for USA and Canada

Possible respiratory problems are diagnosed on evaluation of the following factors:

% Pred FVC	% Pred FEV_1	FEV_1/FVC	Diagnostic Interpretation
-	<75%	<75%	Low FEV_1 suggests obstructive disorder
-	<60%	>=75%	Low FEV_1 suggests ventilatory disorder
<75%	-	>=75%	Low FVC suggests restrictive disorder
<60%	-	<75%	Low FVC suggests ventilatory disorder

If both conditions are satisfied, a Combined Obstructive/Restrictive Ventilatory Defect is indicated. In all other cases, the message "Results appear normal" will be given.

Standards for Countries Outside the USA

ECCS

	Males		Females	
VC	6.103 x H	-0.028 x A -4.654	4.664 x H	-0.024 x A -3.284
FVC	5.757 x H	-0.026 x A -4.345	4.426 x H	-0.026 x A -2.887
FEV1	4.301 x H	-0.029 x A -2.492	3.953 x H	-0.025 x A -2.604
FEV1/SVC		-0.179 x A +87.21		-0.192 x A +89.10
MEF	1.944 x H	-0.043 x A +2.699	1.252 x H	-0.034 x A +2.924
PEF	6.146 x H	-0.043 x A +0.154	5.50 x H	-0.030 x A -1.106
MEF75	5.459 x H	-0.029 x A -0.470	3.218 x H	-0.025 x A +1.596
MEF50	3.794 x H	-0.031 x A -0.352	2.450 x H	-0.025 x A +1.156
MEF25	2.605 x H	-0.026 x A -1.336	1.050 x H	-0.025 x A +1.107

H = Height in meters
A = Age

Quanjer

The Quanjer and Tammeling comparison is valid for children between the ages of 6 and 17 as follows:

	Boys	Girls
SVC = FVC	1.00 x $H^{2.7}$	0.95 x $H^{2.7}$
FEV1	0.84 x $H^{2.7}$	0.81 x $H^{2.7}$
FEV1/SVC	0.84	0.84
MEF = PEF	8.2 x H -6.8	6.6 x H -5.3
MEF50	5.6 x H -4.4	4.6 x H -3.3

H = Height in meters

Austria

The Austrian standard values are valid for children between the ages of 7 and 18 and adults between the ages of 19 and 70 as follows:

BOYS	
Average Values VC = exp (2,786 - 3,08/G + 0,02101 AG) FEV_1 = exp (2,613 - 2,99/G + 0,02080 AG) FEV_1 %VC = 88,5 MVV = 30 FEV_1 TLC = (1,388 - 0,077 G) VC	**Lowest Level Values** VC_{LG} = 0,82 VC FEV_{1LG} = 0,81 FEV_1 FEV_1 %VC_{LG} = 77,6 MVV_{LG} = 0,81 MVV TLC_{LG} = 0,80 TLC

GIRLS	
Average Values VC = exp (3,012 - 3,96/G) $A^{0,2752}$ FEV_1 = exp (3,004 - 4,05/G) $A^{0,2666}$ FEV_1 %VC = 91,5 MVV = 30 FEV_1 TLC = (1,388 - 0,077 G) VC	**Lowest Level Values** VC_{LG} = 0,80 VC FEV_{1LG} = 0,80 FEV_1 FEV_1 %VC_{LG} = 82,0 MVV_{LG} = 0,80 MVV TLC_{LG} = 0,80 TLC

Average Values VC = 12,104 + 8,073G - 0,0406AG + 1,6371 lnA FEV_1 = - 7,205 + 5,997G - 0,0315AG + 0,8745 lnA FEV1 %VC = 104,42 - 20,87 lnG - 0,315A + 0,001611A^2 MVV = 30 FEV_1 TLC = (1,134 + 0,0053A) VC	**Lowest Level Values** VC_{LG} = VC - 1,16 FEV_{1LG} = FEV_1 - 1,01 FEV_1 %VC_{LG} = FEV_1 %VC - 11,0 MVV_{LG} = MVV - 30,6 TLC_{LG} = TLC - 1,60

Average Values VC = - 11,347 + 6,550G - 0,0472AG + 2,0666 lnA FEV_1 = - 7,527 + 5,251G - 0,0382AG + 1,2777 lnA	**Lowest Level Values** VC_{LG} = VC - 0,89 FEV_{1LG} = FEV_1 - 0,82

FEV_1 %VC = 104,23 - 10,9 lng - 0,478A + 0,00264 A^2
MVV = 30 FEV_1
TLC = (1,2413 + 0,0036 A) VC

FEV_1 $\%VC_{uG}$ = FEV_1 %VC - 11,3
MVV_{uG} = MVV - 24,6
TLC_{uG} = TLC - 1,20

G = Height in meters
A = Age
uG = Lowest level
exp = e-function
n = natural logarithm

Swedish (Berglund)

The Swedish (Berglund) standard is valid for adults between the ages of 18 and 75 years as follows:

	Males	Females
FEV%	91.79 -(0.373 x A)	92.11 -(0.261 x A)
SVC	1.09 [(4.81 x H) -(0.020 x A) -2.81]	1.09 [(4.04 x H) -(0.022 x A) -2.35]
$FEV_{1.0}$	1.09 [(3.44 x H) -(0.033 x A) -1.00]	1.09 [(2.67 x H) -(0.027 x A) -0.54]

A = Age
H = Height in meters

Finnish

The Finnish standard is valid for adults from the age of 18 years as follows:

Males	
SVC (l)	exp [(-0.00833 x A) + (0.6309 x log A) + (-1.4750 / H) + 0.9047]
FEV_1 (l)	exp [(-0.00587 x A) + (0.2756 x log A) + (-1.1655 / H) + 1.0980]
FVC (l)	exp [(-0.00827 x A) + (0.5860 x log A) + (-1.4468 / H) + 0.9461]
FEV_1 / SVC (%)	exp [(0.00246 x A) + (-0.3553 x log A) + (0.3095 / H) + 2.1933]
FEV_1 / FVC (%)	exp [(0.00240 x A) + (-0.3104 x log A) + (0.2813 / H) + 2.1519]
PEF (l/s)	exp [(-0.00211 x A) + (0.1049 x log A) + (-0.6774 / H) + 1.3255]

Females	
SVC (l)	exp [(-0.01016 x A) + (0.6995 x log A) + (-1.4518 / H) + 0.7763]
FEV_1 (l)	exp [(-0.00920 x A) + (0.4772 x log A) + (-1.3284 / H) + 0.9296]
FVC (l)	exp [(-0.00982 x A) + (0.6358 x log A) + (-1.4137 / H) + 0.8320]
FEV_1 / SVC (%)	exp [(0.00096 x A) + (-0.2223 x log A) + (0.1233 / H) + 2.1533]
FEV_1 / FVC (%)	exp [(0.00062 x A) + (-0.1586 x log A) + (0.0853 / H) + 2.0975]
PEF (l/s)	exp [(-0.00677 x A) + (0.4017 x log A) + (-0.7422 / H) + 0.9661]

A = Age
H = Height in meters
log = Log to base 10

Standards for USA and Canada

Morris

The Morris equations are valid for women between 56 and 72 inches tall and within the age range of 20 to 90 years, and for men between 58 and 80 inches tall and within the age range of 20 to 90 years as follows:

	Males	Females
FVC	0.1480 x H -0.0250 x A -4.241	0.1150 x H -0.0240 x A -2.852
FEV_1	0.0920 x H -0.0320 x A -1.260	0.0890 x H -0.0250 x A -1.932
FEV_1/FVC	-0.3118 x H -0.2422 x A +107.120	-0.0679 x H -0.1815 xA +88.700
$FEF_{0.2-1.2}$	0.1090 x H -0.0470 x A +2.010	0.1450 x H -0.0360 x A -2.532
FEF_{25-75}	0.0470 x H -0.0450 x A +2.513	0.0600 x H -0.0300 x A +0.551
FEF_{75-85}	0.0130 x H -0.0230 x A +1.210	0.0250 x H -0.0210 x A +0.321

The Morris normals are extended with the following ITS equations:

	Males	Females
$FEV_{0.5}$	0.0831 x H -0.0152 x A -1.914	0.0605 x H -0.0185 x A -0.809
$FEV_{3.0}$	-0.1359 x H -0.0271 x A -3.512	-0.1123 x H -0.0257 x A -2.745
$FEV_{3.0}$/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160
MVV	3.4040 x H -1.2600 x A -21.400	2.0500 x H -0.5700 x A -5.500

H = Height in inches
A = Age in years

Crapo

The Crapo equations are valid for men between 61 and 77 inches tall and within the age range of 18 to 89 years, and for women between 57 and 71 inches tall and within the age range of 18 to 89 years as follows:

	Males	Females
FVC	0.1524 x H -0.0214 x A -4.650	0.1247 x H -0.0216 x A -3.590
FEV_1	0.1052 x H -0.0244 x A -2.190	0.0869 x H -0.0255 x A -1.578
FEV_3	0.1359 x H -0.0271 x A -3.512	0.1123 x H -0.0257 x A -2.745
FEV_1/FVC	-0.3302 x H -0.1520 x A +110.490	-0.5131 x H -0.2520 xA +126.580
FEF_{25-75}	0.0518 x H -0.0380 x A +2.133	0.0391 x H -0.0460 x A +2.683
MVV Vol.	3.4040 x H -1.2600 x A -21.400	2.0500 x H -0.5700 x A -5.500

The Crapo normals are extended with the following ITS equations:

	Males	Females
$FEV_{0.5}$	0.0831 x H -0.0152 x A -1.914	0.0605 x H -0.0185 x A -0.809
$FEV_{3.0}$/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160

H = Height in inches
A = Age in years

Knudson

The Knudson equations are valid for both children and adults in specific groups according to age and height as follows:

	Males	Females
	H = 44 to 61 inches, A = 6 to 11 yrs	**H = 42 to 58 inches, A = 6 to 10 yrs**
FVC	0.1039 x H +0.0 x A -3.376	0.1092 x H +0.0 x A -3.749
$FVC_{0.5}$	0.0760 x H +0.0430 x A -3.050	0.0480 x H +0.0610 x A -1.740
FEV_1	0.0884 x H +0.0 x A -2.814	0.0853 x H +0.0 x A -2.758
FEV_1/FVC	-0.2065 x H +0.0 x A +100.439	-0.4849 x H +0.6655 x A +109.974
FEF_{25-75}	0.0859 x H +0.0 x A -2.320	0.0559 x H +0.0 x A -0.812
PEF	0.1980 x H +0.1660 x A -8.061	0.1240 x H +0.1570 x A -3.920
FEF_{50}	0.0960 x H +0.0 x A -2.545	0.0 x H +0.1846 x A +0.736
FEF_{75}	0.0434 x H +0.0 x A -1.015	0.0277 x H +0.0 x A -0.166
MVV	3.0300 x H -0.8160 x A -37.900	2.7600 x H -3.4000 x A -108.120
	H = 55 to 76 inches, A = 12 to 25 yrs	**H = 52 to 72 inches, A = 11 to 20 yrs**
FVC	0.1499 x H +0.0739 x A -6.887	0.1057 x H +0.0699 x A -4.447
$FVC_{0.5}$	0.0760 x H +0.0430 x A -3.050	0.0480 x H +0.0610 x A -1.740
FEV_1	0.1318 x H +0.0636 x A -6.118	0.0892 x H +0.0694 x A -3.762
FEV_1/FVC	-0.2065 x H +0.0 x A +100.439	-0.4849 x H +0.6655 x A +109.974
FEF_{25-75}	0.1369 x H +0.0749 x A -6.199	0.0709 x H +0.1275 x A -2.801
PEF	0.1980 x H +0.1660 x A -8.061	0.1240 x H +0.1570 x A -3.920
FEF_{50}	0.1379 x H +0.1150 x A -6.385	0.0732 x H +0.1111 x A -2.304
FEF_{75}	0.1008 x H -0.0057 x A -4.242	
MVV	4.6800 x H +1.8000 x A -192.320	2.7600 x H -3.4000 x A -108.120
For patients ove r 18 yrs, the following ITS equations apply:		
$FEV_{3.0}$	0.1359 x H -0.0271 x A -3.512	0.1123 x H -0.0257 x A -2.745
$FEV_{3.0}$/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160
	H = 62 to 77 inches, A = 26 to 120 yrs	**H = 58 to 71 inches, A = 21 to 120 yrs**
FVC	0.1524 x H -0.0214 x A -4.650	0.1247 x H -0.0216 x A -3.590
$FVC_{0.5}$	0.0831 x H -0.0152 x A -1.914	0.0605 x H -0.0185 x A -0.809
FEV_1	0.1052 x H -0.0244 x A -2.190	0.0869 x H -0.0255 x A -1.578
$FEV_{3.0}$	0.1359 x H -0.0271 x A -3.512	0.1067 x H -0.0257 x A -2.745
FEV_1/FVC	0.0 x H -0.1050 x A +86.686	-0.4704 x H -0.1896 x A +121.678
$FEF_{0.2-1.2}$	0.1090 x H -0.0470 x A +2.010	0.1450 x H -0.0360 x A -2.532
FEF_{25-75}	0.1471 x H -0.0363 x A -4.518	0.0531 x H -0.0344 x A +1.128
FEF_{75-85}	0.0130 x H -0.0230 x A +1.210	0.0250 x H -0.0210 x A +0.321
PEF	0.2390 x H -0.0350 x A -5.990	0.1240 x H -0.0250 x A -0.740
FEF_{25}	0.0900 x H -0.0200 x A +2.726	0.0690 x H -0.0190 x A +2.147
FEF_{50}	0.1737 x H -0.0366 x A -5.409	0.0681 x H -0.0289 x A +0.609
FEF_{75}	0.0787 x H -0.0230 x A -2.483	0.0244 x H -0.0259 x A +1.118
MVV	3.0300 x H -0.8160 x A -37.900	2.1400 x H -0.6850 x A -4.870
In addition, there are the following ITS equations:		
$FEV_{3.0}$/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160

H = Height in inches
A = Age in years

Composite

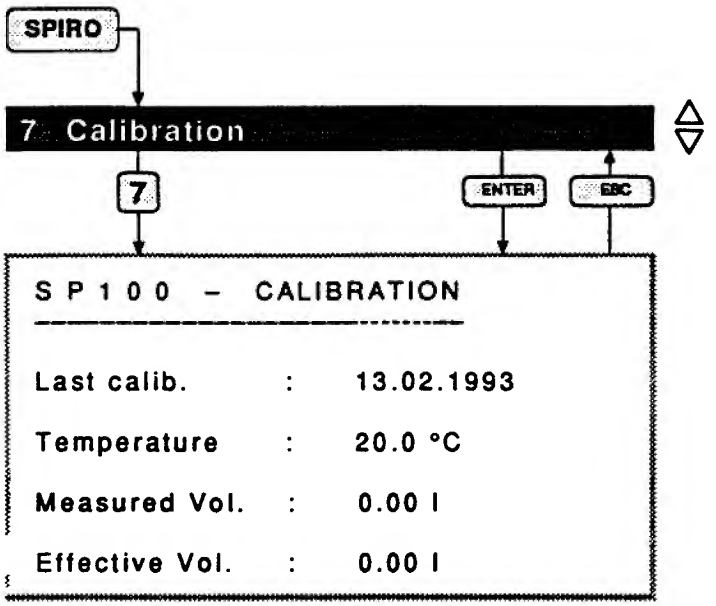
Selection of the Composite normals provides selected equations taken from other tables as follows:

Value	Equation Reference
FVC	Knudson
FEV_1	Knudson
FEV_3	Crapo
FEF_{25-75}	Knudson
FEF_{75-85}	Morris
$FEF_{0.2-1.2}$	Morris
MVV	Crapo
SVC	Knudson (same as FVC)

Calibration of the Flow Sensor

Use of the Calibration Pump

Before starting a series of tests, it is advisable to calibrate the unit using the calibration pump. To call up the calibration menu, press the following keys:



The cursor is on the line for the input of the ambient temperature (in America, the temperature is given in °F). Input the temperature and press **ENTER**.

Insert the calibration pump into the rubber adapter, press **AUTO START**, and pump 2 to 6 litres of air.

NOTE: *Make sure that the flow sensor is kept still during the pumping operation.*

While pumping, the unit records the actual volume being pumped through the flow sensor which is indicated on the display.

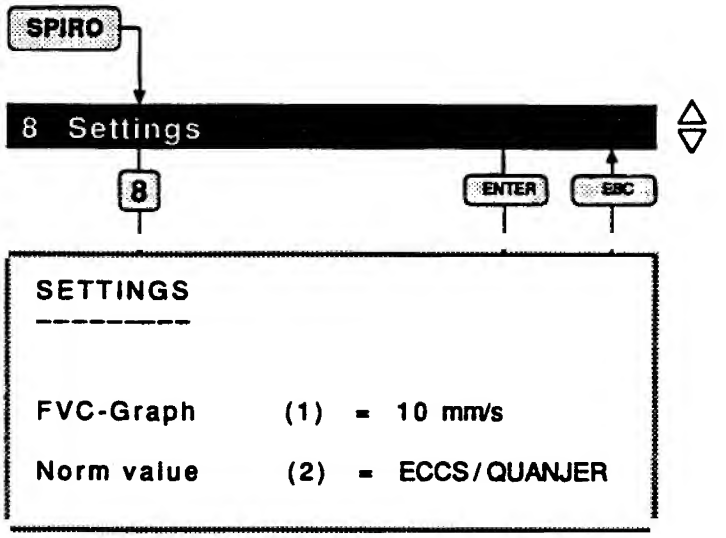
At the end of the pumping operation, press **ENTER** and the cursor moves down for the input of the effective volume. Enter this volume and press **ENTER**. The unit then calculates the calibration factor (accepted deviation ±25%).

In the event that the calibration cannot be successfully carried out and an error message appears on the display, then exit the calibration menu by pressing **FNCT**. Re-select calibration, then press **I** to return the unit to its base calibration (or zero) setting. Now carry out the calibration procedure as described before.

Once the message "Calibration completed" appears on the display, press **COPY** and a calibration report is printed out. Press **FNCT** to return to the main menu.

Settings for the Calibration

For settings, press the following keys:



Select in the menu:

- **FVC-Graph** **(1):** Select between: 10 mm/s
  20 mm/s
  With this the FVC graph presentation settings on the printout ore made.

- **Norm value** **(2):** Select between: ECCS/QUANJER
  INDIAN
  With this the measurement calculation standards are made.

Care and Maintenance

The utmost attention must be paid to the cleanliness of the flow sensor. Because the patients must breathe through the nozzle (inhaling as well as exhaling), it is important that the mouthpiece and filter be renewed and the measuring tube painstakingly cleaned and sterilised before the next patient uses the device.

Cleaning and Sterilising the Flow Sensor

To clean the flow sensor, proceed as follows:

1. Remove and discard the mouthpiece.
2. Remove the rubber adapter by pulling it away from the inner tube.
3. Remove the inner tube of the flow sensor by pushing it out of the outer tube in the direction of the red location marks. Once the tube has been pushed half way it can be pulled out from the other side.
4. Unscrew the two halves of the inner tube and remove and discard the filter.
5. Clean and sterilize all parts of the inner tube, the rubber adapter and the inside of the outer tube with one of the following products:
   - Incidin GG
   - Amocid
   - Lysoformin
   - Alhydex
6. The cable and handle can be wiped with soapy water (do not dip into liquid!).

Reassembling the Flow Sensor

To reassemble the flow sensor, proceed as follows:

1. Insert a new filter into the inner tube so that it sits on the inner lip of the half with the red location mark.
2. Carefully screw the two halves of the inner tube together making sure that the filter is not displaced.
3. Locate the end of the inner tube into the end of the outer tube and push it gently but firmly until the shoulder of the inner tube makes contact on the outside edge of the outer tube. **The two red location marks must be together.**
4. Fit the rubber adapter by placing its wider end over the end of the inner tube with the red location mark.
5. Insert a new mouthpiece (max. 1.5cm) into the end of the rubber adapter.

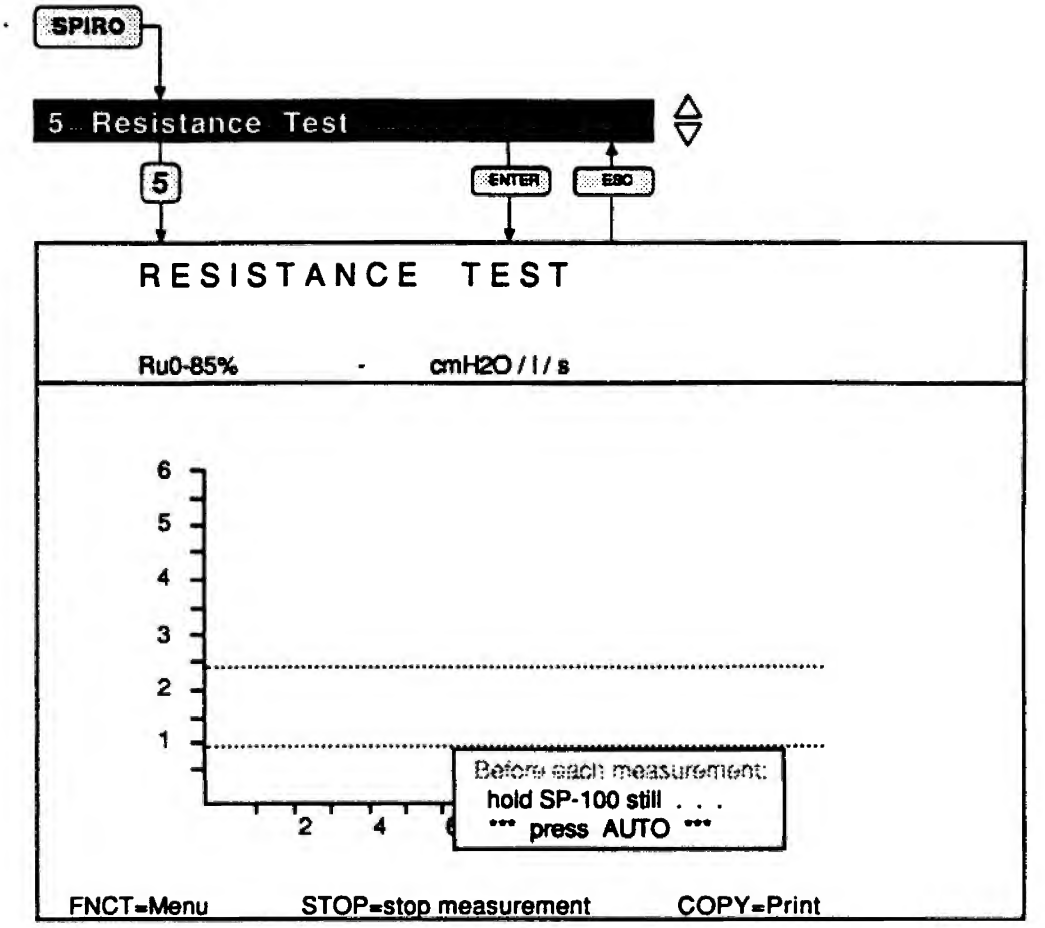
The flow sensor is now ready for use.

Resistance Measurement with Flow Sensor SP-110/R

Resistance measurement enables the early detection of an obstruction in the respiratory tract through measurement of the lung pressure necessary for exhalation.

Execution of Resistance Test

To call up the expiration resistance test, select "Resistance Test" when in the main Pulmonary Testing menu and the corresponding coordinates appear on the display as in the following example:



The display indicates that an average resistance value will be measured between 0 and 85% of the expired volume of air. To the right, the actual measured resistance will be given as a pressure value in cm H_2O / litre / second. The coordinates represent the graph on which the curve will be drawn with the expiratory flow on the vertical axis and the time in seconds on the horizontal axis.

The patient should inhale as deeply as possible before starting the test and then exhale through the flow sensor in such a way that the curve on the display remains between the two horizontal markers (i.e. between 1 and 2.5 litres). This may require several trial runs before the patient achieves the necessary flow of exhaled air so make sure that he is aware of this and that he understands what is required of him.

NOTE: *At regular intervals during exhalation, the air flow will be interrupted for very short periods. If the air flow is too strong (>2.5 l/s) then the shutter could become blocked and the measurement invalidated.*

Printed Informations with Resistance Test

The printout following a resistance test contains the following informations:

- Resistance curve (resistance as a function of volume)
- The measured pressure as cmH_2O / litre / second

Where an SVC test has also been carried out, the ERV and EV values appear together with the resistance value of the expired volume at ERV.

Cleaning and Assembling the Resistance Sensor

With each resistance test, a build-up of condensation is created within the resistance sensor of the flow sensor. This should be wiped dry after each patient.

Cleaning

To clean the resistance sensor, proceed as follows:

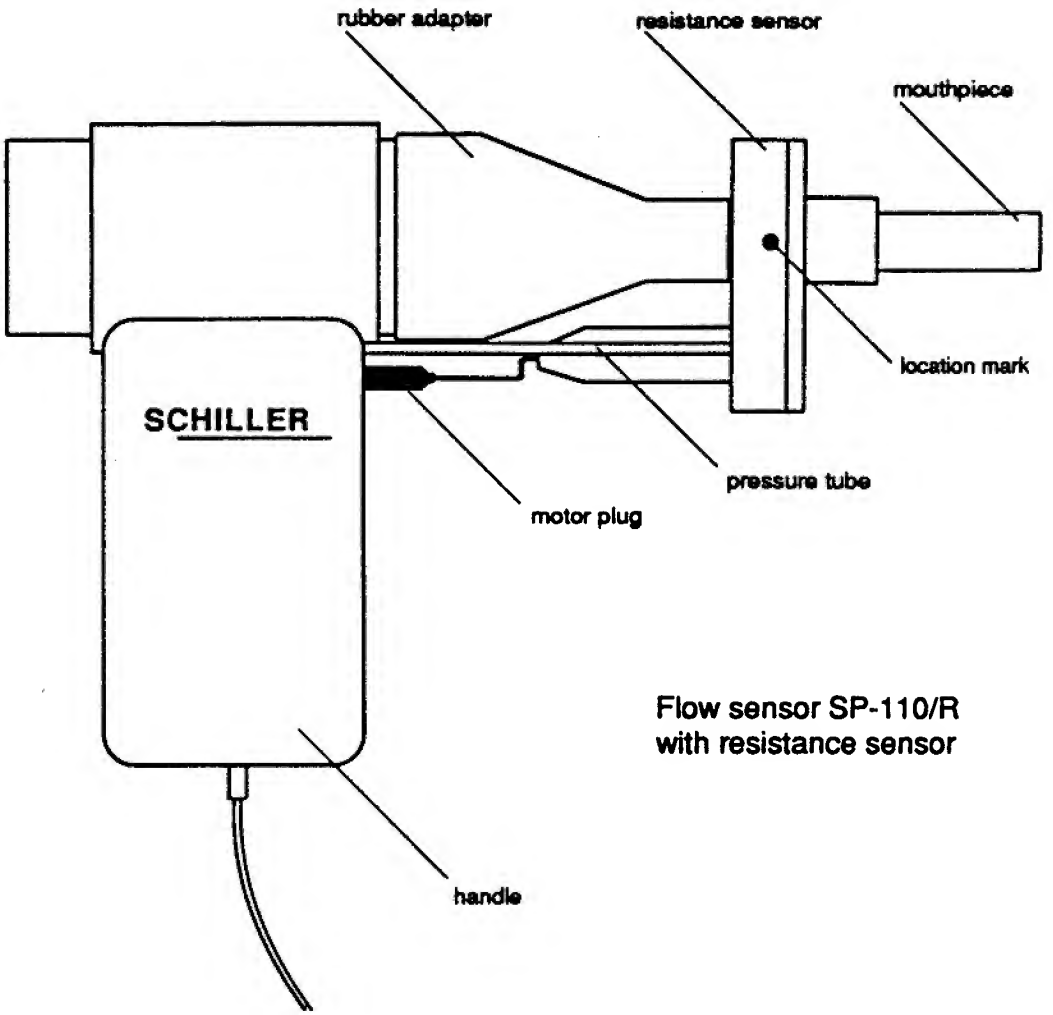
1. Remove and discard the mouthpiece.
2. Disconnect the pressure tube and motor plug from the handle.
3. Pull the resistance sensor out of the rubber adapter.
4. Separate the two halves of the resistance sensor, making sure that the shutter does not fall out.
5. The condensation can now be wiped away with a soft absorbent cloth. The two halves of the resistance sensor and the shutter can also be sterilised with one of the following products:
   - Incidin GG
   - Anocid
   - Lysoformin
   - Alhydex

Assembleing

To reassemble the resistance sensor, proceed as follows:

1. Check that the shutter is in place and reassemble the two halves of the sensor making sure that the two air tube apertures are on the same side. Press lightly until the two halves click together.
2. Insert the air tube into the rubber adapter ensuring that the pressure tube and motor plug are on the under side and pointing in the direction of the flow sensor handle (red location mark to the left).
3. Slide the pressure tube over the connection on the handle of the flow sensor.
4. Plug the motor plug into the socket on the handle of the flow sensor.
5. Insert a new mouthpiece.

The resistance sensor is now ready for use.



Flow sensor SP-110/R
with resistance sensor

Technical Data SP-100/R (SP-110/R)

Method of measurement:	pneumotachometer
Measurement ranges:	flow: 0 to ± 15 l/s
	volume: 0 to ± 11 l
Measurement accuracy:	± 2%
Flow impedance:	less than $\frac{0.5 \text{ mbar} \cdot \text{s}}{\text{l}}$ at 10 l/s
Measured values:	VC, ERV, IRV, TV, FVC, $FEV_{0,5}$, $FEV_{1,0}$, $FEV_{3,0}$, $FEV_{0,5}$/VC, $FEV_{1,0}$/VC, $FEV_{3,0}$/VC, $FEF_{0,2\text{-}1,2}$ (Liter), $FEF_{25\text{-}75\%}$, $FEF_{75\text{-}85\%}$, PEF, $MEF_{75\%}$, $MEF_{50\%}$, $MEF_{25\%}$, MV, MVV, FIVC, $FIV_{1,0}$, $FIV_{1,0}$ /FIVC, $FIV_{1,0}$/FVC, PIF, $MIF_{50\%}$
	Comparison pre/post medication possible.
Prediction equation:	adults: ECCS / Berglund / Finnish / Indian / Morris / Crapo / Knudson
	children: Quanjer & Tammeling / Indian / Knudson

(Technical data subject to change without notice)

Spirometry Accessories

Standard accessories		**Art. No.**
•	For AT-60:	
1	pneumotacho sensor SP-100	2.100015
•	For AT-10:	
1	pneumotacho sensor SP-110	2.200510
• 100	disposable cardboard mouthpieces	2.100024
• 2	nose clips	2.100084
• 10	filters	2.100026
•	spirometer software (To be installed by your authorised service representative. When ordering an AT-10 / AT-60 with spirometer option, the software is already installed.)	

Optional accessories	**Art. No.**
• For AT-60:	
pneumotacho sensor SP-160 (disposable flow sensors)	2.200530
resistance sensor SP-100/R	2.100016
• For AT-10:	
pneumotacho sensor SP-150 (disposable flow sensors)	2.200520
resistance sensor SP-110/R	2.200511
• flow sensors for SP-150/SP/160 (set of 10 pcs)	2.100077
• calibration pump	2.100027

Option 7

Late Potential Analysis

CONTENTS

Introduction

Late potentials are high-frequency, low-amplitude signals at the end of the QRS complex. With an amplitude of about 10µV, these micropotentials are about 100 times smaller than the QRS amplitude (about 1mV). Late potential are therefore not detectable in a normal ECG.

Research has shown that late potentials at the end of the QRS complex may be correlated with an increased risk of ventricular arrythmias and sudden cardiac death.

Analysis of Cardiac Cycles

In order to improve the signal-to-noise ratio, and hence detect late potentials, a series of cardiac cycles (a minimum of 100 is recommended) have to be recorded and averaged for the purposes of analysis and comparison. When examining a patient for late potentials he should be aware that the process demands a certain amount of time and that during the recording he should remain in the recumbent position.

The averaging of about 100 heart beats improves the signal-to-noise ratio by a factor of 10. High-pass filtering of the averaged ECG signals permits high frequency, low-amplitude late potentials to be detected reliably.

Carrying Out Late Potential Analysis

Analysis Basis

The SCHILLER Late Potential Analysis program analyses the signals either from the data of the 12 simultaneous standard leads (of the normal resting ECG recording) or from the ECG data of the orthogonal Frank XYZ leads. For the position of the corrected XYZ leads, see illustration in Chapter 2).

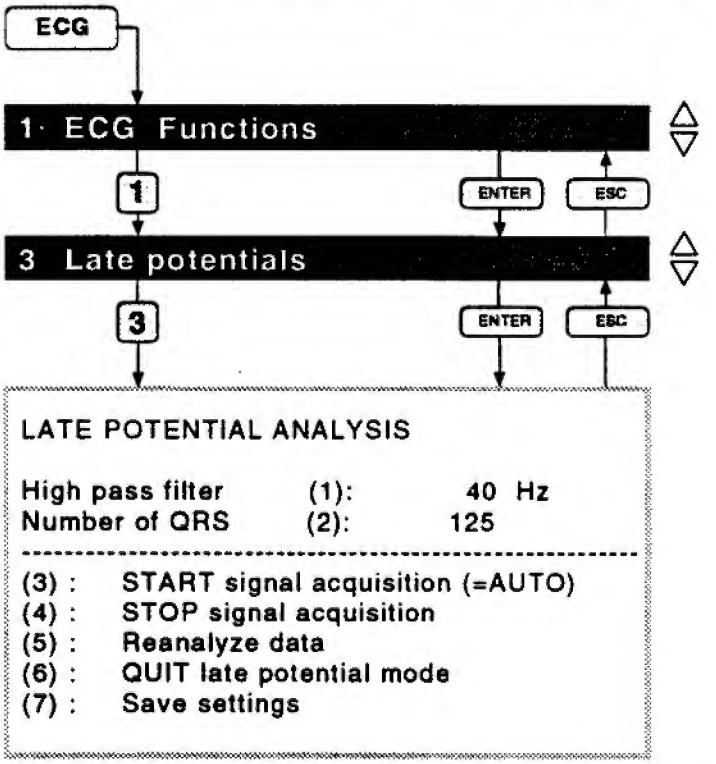
Activate Late Potential Mode

Prerequisites

The electrodes are attached in the correct positions and the required lead configuration (i.e. 12 Standard or XYZ lead) has been selected.

Menu Selections

To access the menu for the late potential analysis, press the following keys:



1. By pressing the number indicated in parenthesis make the following selections:
   - **High pass filter:** (1): Select between: 25Hz
     40Hz
     80Hz

     Key 1 selects the cut-off frequency of the high-pass filter .

- **Number of QRS:** (2): Select between: 0...300Hz
  in steps of 25Hz

  Key **2** selects the number of QRS complexes to be taken into account for analysis.

2. After the settings have been made, start signal acquisition by pressing key **3**.

   NOTE:

   After having attached the last electrode, wait at least 20 seconds before pressing key 3 in order to prevent possible baseline wandering.

   During data acquisition, the number of cardiac cycles accepted for averaging (QRS acc) and those rejected (QRS rej) together with the actual noise level (Noise µV) are continually updated and displayed at the top of the screen.

3. To stop signal acquisition press key **4**.
   This interrupts data acquisition and starts the automatic analysis. This process is concluded with a print-out of the precise analysis results.

Since the data remains in the unit memory, it can be re-evaluated by selecting a new high pass filter setting. Press key **1** to select a new cut-off frequency and then press key **5** (re-analyse data). The results of this analysis will be given in a new printout.

To exit the late potential analysis program without printout of results, press key **6**. Alternatively, press key **2nd** and **ECG.**

NOTE: *Once key **6** has been pressed, the recorded data is immediately erased from the unit memory and is therefore no longer available for further processing or printing.*

To save the settings made, press key **7**.

Late Potential Analysis Reports

The printout at the end of the signal acquisition process comprises 2 pages for the XYZ leads calculated on the basis of the 12 standard leads. The first page provides the late potential results for each of the derived XYZ leads (derived when working with the standard lead configuration in accordance with the Simson method). The second page provides the individual late potential results for each of the 12 leads.

For directly measured XYZ leads (when working with the XYZ lead configuration), the first page provides the standard late potential results for each of the actual XYZ leads. The second page is not printed out.

Signal Presentation

The signal presentation on the printout is as follows (from left to right):

- averaged QRS complex (ranging from 0.05 to 250Hz)
- averaged QRS complex (ranging from the selected high pass filter setting up to 250Hz)
- Vector magniture for the entire high frequency content of the signal (RMS) across all three XYZ leads

The following indications are given at the bottom of the printout:

- patient data
- noise level during signal acquisition
- number of QRS complexes accepted for averaging (QRS acc) and those not accepted for averaging due to non-correlation (QRS rej)

- heart rate (HR)
- Late Potential analysis results (see below)
- high frequency content of the signal and noise given for each of the actual or derived leads (LAHFd, noise)
- remarks in case of derived XYZ leads (X,Y,Z: derived)

Measurement Results

The following measurement results are given:

- **QRS duration** — the duration of QRS given in ms
- **HF QRS duration** — the duration of QRS given in ms as determined from the high frequency portion of the signal (starting at the first dotted line and ending at the last dotted line)
- **RMS (40ms)** — the root mean square value of the high frequency signal of the last 40ms of the ventricular activation (starting at the dashed line and ending at the last dotted line)
- **RMS (50ms)** — the root mean square value of the high frequency signal of the last 50ms of the ventricular activation (starts 50ms before the last dotted line, no marking)
- **LAHFd (40µV)** — the duration of the high frequency, low amplitude portion at the end of the QRS cycle (LAHFd = Low Amplitude High Frequency duration, starts at the dotted line which marks the point where the signal drops below 40 µV and ends at the last dotted line)

These results should be evaluated in conjunction with the high frequency averaged QRS complex curves and not in isolation (e.g. look at the curves in order to verify that the beginning and end of QRS have been correctly determined).

The **second** page (when working with the standard lead configuration) provides the individual late potential results for each of the 12 leads. The averaged QRS complex together with the high frequency content is shown for each lead. This report will be useful for the purposes of verifying whether or not the late potential duration is markedly longer in one of the leads than in the vector magnitude.

Data Evaluation

Criteria for the Presence of Late Potentials

Frequency range of 25 to 250Hz

According to conventional limits (Simson and McFarlane: The Signal-averaged Electrocardiogram, in "Comprehensive Electrocardiology", Pergamon Press, 1989) the following limits are valid as indication of the presence of late potentials for a signal in the frequency range of 25 to 250Hz:

QRS duration	> 110ms
LAHFd	> 30ms
RMS-40ms	< 25µV

Frequency range of 40 to 250Hz

The following limits are valid for the presence of late potentials for a signal in the frequency range of 40 to 250Hz (G. Breithardt, M. E. Cain, N. El-Sherif, N. C. Flowers, V. Hombach, M. Janse, M. B. Simson, G. Steinbeck: Standards for Analysis of Ventricular Late Potentials Using High-resolution or Signal-averaged Electrocardiography, Journal of the American College of Cardiology, No. 5:999-1006):

QRS duration	> 114ms
LAHFd	> 38ms
RMS-40ms	< 20µV

IMPORTANT: *These criteria do not relate to patients with blocks with a prolonged QRS duration. The noise level after averaging should be lower than 1µV.*

Option 8

Heart Rate Variability

CONTENTS

Introduction

This new software development from SCHILLER permits the risk of sustained ventricular tachycardia and of sudden cardiac death to be better accessed by analysing the heart rate regularity , i.e. RR variability.

At present, these kind of examinations are performed with patients after myocardial infarction, in order to assess the risk of sudden cardiac death, and with diabetics, in order to detect autonomous neuropathy.

Patients suffering from certain diseases show a significantly reduced RR variability. In the past, a 24-hour ECG was required to determine such a reduced RR variability. With the SCHILLER analysis program, it is now possible to determine the RR variability by measuring either 512 or 1024 heart beats (i.e. within 10 to 20 minutes).

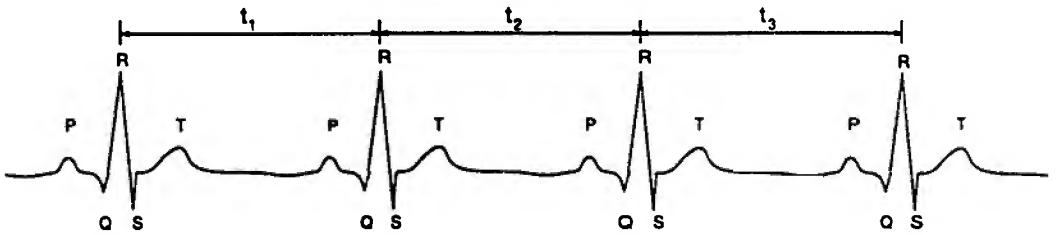
The SCHILLER software is based on the most recent findings from research and technology. None of our competitors offers this kind of analysis in such a comprehensive and accurate form.

In the following, the new RR variability software is presented in more details.

Basics of Heart Rate Variability

The heart rate is not a permanently constant value, but variable within certain limits; a completely regular heart rate may even be considered pathological.

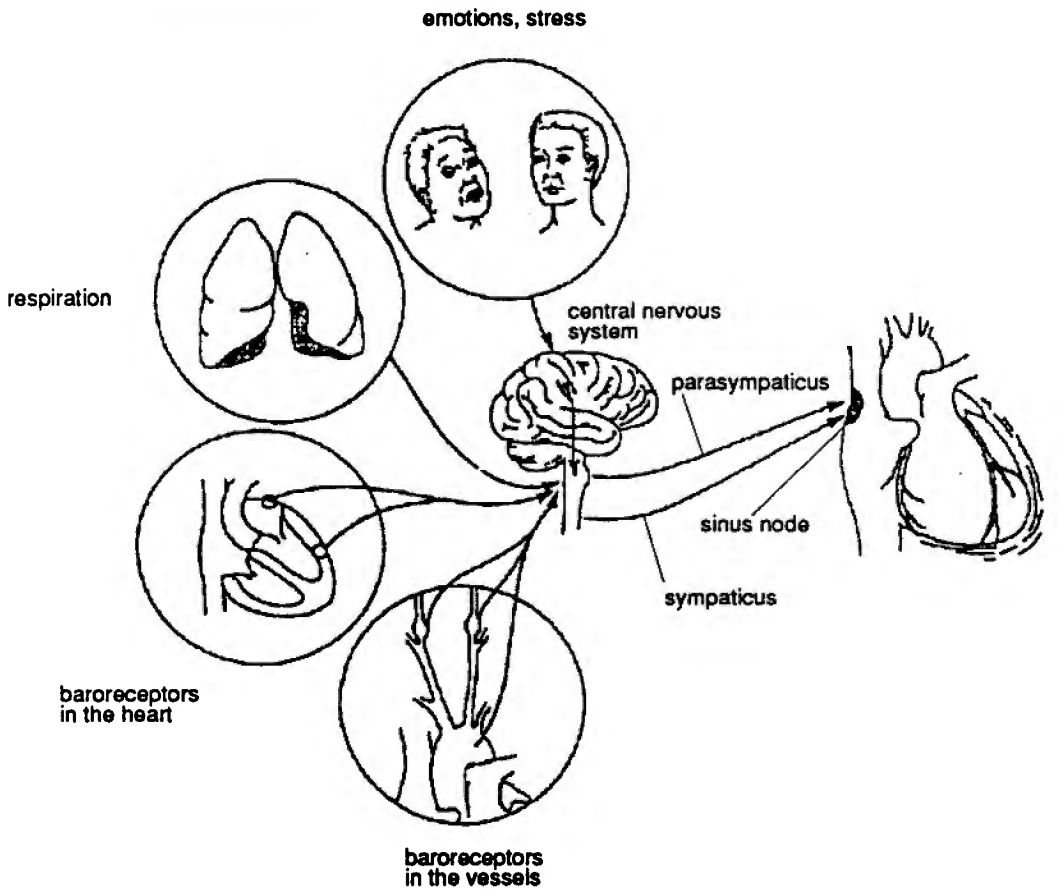
In order to measure heart rate variability, RR intervals are determined during sinus rhythm, in periods without rhythm disturbances (see intervals t_1, t_2, t_3 ...).



Heart rate regularity is, among other factors, influenced by the sympathetic and parasympathetic nerves (e.g. by the autonomous nervous system) which regulate physiological variations in the body.

Sinus node and therefore heart rate are stimulated by the sympathetic nerve and inhibited by the parasympathetic nerve. A further important factor influencing RR variability (heart rate variability) is respiration.

Influencing Factors



Respiration

During inspiration, the RR interval is decreasing (i.e. heart rate is increasing), during expiration, the RR interval is increasing (i.e. heart rate is decreasing). This physiologically normal variation of the RR interval is called respiratory arrhythmia, showing the highest extent with children and decreasing with age.

Further Factors

Apart from respiration, further factors such as varying arterial blood pressure and psychical and physical condition of the patient also influence the heart rate.

In order to exclude influence on RR variability by physical stress or emotions, the patient should relax completely during examination.

Results from Long-term ECG Examinations

According to studies on long-term ECG examinations, the risk to die from sudden cardiac death after myocardial infarction is five times higher for patients with a RR variability below 50 ms than for patients with a higher variability.

A reduced RR variability therefore indicates an increased risk of sudden cardiac death (similar to the detection of ventricular late potentials). A reduced RR variability in patients suffering from cardiac diseases also indicates a high risk for sustained ventricular tachycardia.

Furthermore, the determination of heart rate variability (especially the frequency analysis) permits assessment of the balance between sympathetic and parasympathetic nerve.

This balance is disturbed not only in patients suffering from cardiac diseases, but also in diabetics with autonomous neuropathy. These diabetics - similar to patients susceptible to die from sudden cardiac death - show a significantly reduced RR variability.

Selectable Parameters Before the Analysis

Before starting the measurement the following parameters can be selected:

- FFT window type
  (type of signal limitation in time domain before Fourier Transformation: rectangular, Hanning, Blackman-Harris window type)
- number of RR intervals to be measured
  (512 or 1024)
- FFT type
  (type of preparation and standardization of RR intervals before Fourier Transformation is applied)

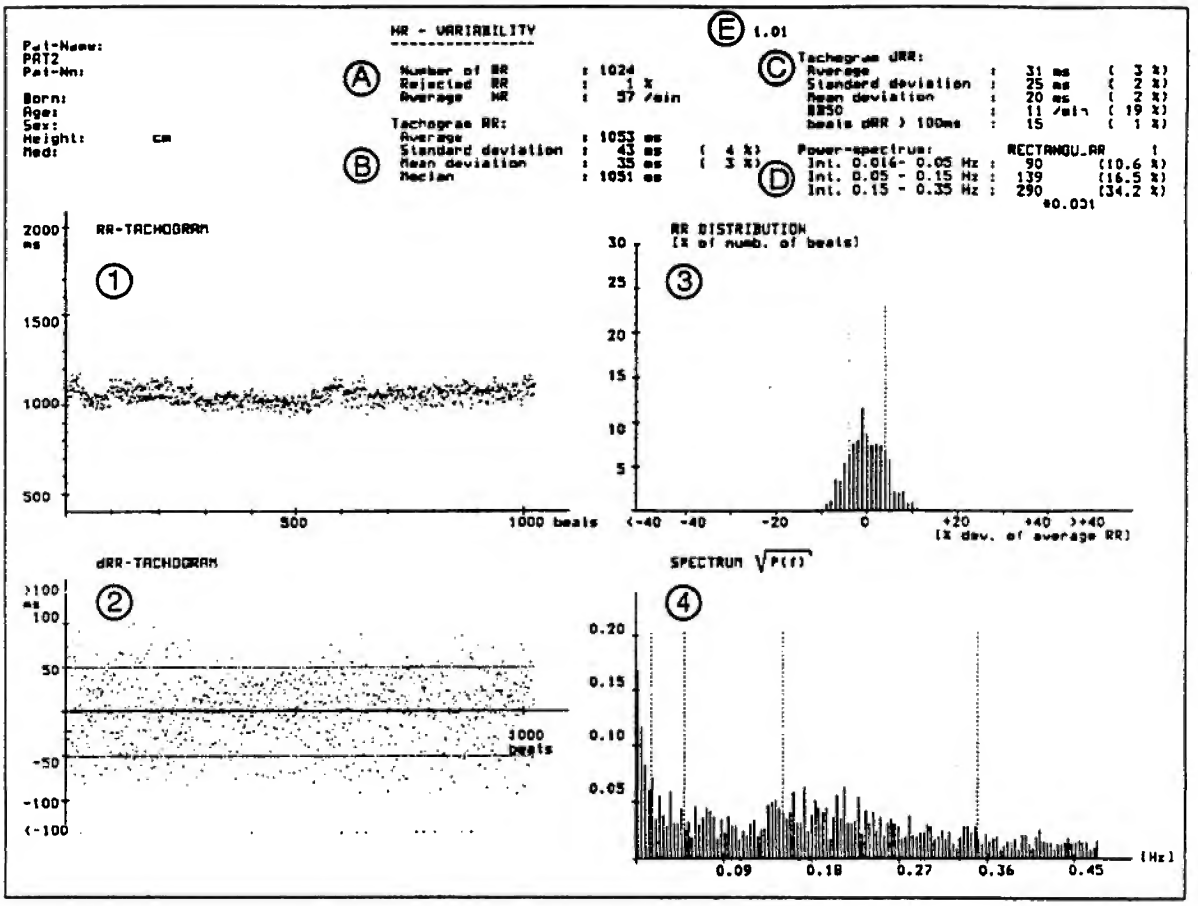
  For a detailed description of the above parameters, see "Frequency Analysis" later in this chapter.
- Phase-space plots (option for the printout)

  For a detailed description see "Phase-space plots" later in this chapter.

Details of the RR Analysis

The software version of the RR analysis program is indicated below at Ⓔ

Printed Diagrams



Interpreted Parameters During Analysis

In the above diagrams you find at Ⓐ following parameters:

- Number of measured RR intervals
  (512 or 1024)
- Percentage of rejected RR intervals
  (after triggering, correlation found too low)
- Average heart rate
  (in beats per minute)

Comments on Diagrams

RR Tachogram

The diagram at ① shows the

RR interval (Y axis in ms) for the examined heart beat (X axis, number of beats)
(i.e. Heart rate 500 with RR interval 1000ms)

Belonging to the RR tachogram are the informations at Ⓑ:

Average value m

$m = {}^{1}/_{n} * (t_1 + t_2 \ldots\ldots + t_n)$ of examined RR intervals $t_1, t_2, \ldots\ldots, t_n$

Standard deviation s of these RR intervals

$$s = \sqrt{{}^{1}/_{(n-1)} * ((t_1 - m)^2 + (t_2 - m)^2 + \ldots + (t_n - m)^2)}$$

Average (absolute) deviation d

$$d = {}^{1}/_{n} * (|t_1 - m| + |t_2 - m| + \ldots\ldots + |t_n - m|)$$

Median

50% of all values are above and 50% below this value. In a symmetrical distribution this value equals average value.
If the two values do not correspond to each other, the distribution of the RR intervals is not symmetrical.

NOTE: *All values are also indicated as percentage of the average RR interval. This important parameter is only offered by SCHILLER!*

dRR Tachogram

The diagram at ② shows the **difference** of the RR intervals between subsequent heart beats, i.e.:

$dt_1 = t_1 - t_2$ (Difference between the first and second RR interval)

$dt_2 = t_2 - t_3$ (Difference between the second and third RR interval)

$dt_3 = t_3 - t_4$ (Difference between the third and fourth RR interval)

etc.

These difference (delta) values (in distinction to RR, here called dRR) are presented in the graph dependent upon the number of heart beats.

The limit value in the graph is 50ms.

Conclusion: *If all difference values of subsequent RR intervals remain within this range, heart rhythm is considered very rigid and therefore, according to actual studies, probably pathological.*

Belonging to the dRR tachogram are the informations at Ⓒ for the statistical interpretation:

Average values

Standard deviation

Average deviation of RR variability

BB50 (beat-to-Beat-50ms)
Number of beats with the difference from beat to beat exceeding 50ms (indicated in beats per minute).

The lower the BB50 value, the higher the extent of pathology in diagnosis.

Beats dRR > 100ms
Number of beats with variability exceeding 100ms. Information is also given in percents of the average RR interval, as for different heart rates, different standard limit values may be applicable.

Frequency Distribution

The diagram at ③ shows the

Frequency distribution of RR intervals examined, with reference to the average RR interval (indicated at x = 0), and percental deviations.

The dotted lines mark standard deviations. According to Gauss, in normal distribution, 68 % of all values remain within the value range of this double standard deviation. The graph also shows to which extent distribution of RR intervals is symmetrical.

Frequency Spectrum

The diagram at ④ shows the spectrum.

After frequency analysis (with Fast Fourier Transformation FFT), distribution of RR intervals is presented within frequency domain (and no longer within time domain, as before). Influences from the autonomous nervous system by the sympathetic or the parasympathetic nerve may be distinguished, and any disturbances in their mutual balance detected.

Spectral high frequency limit is:

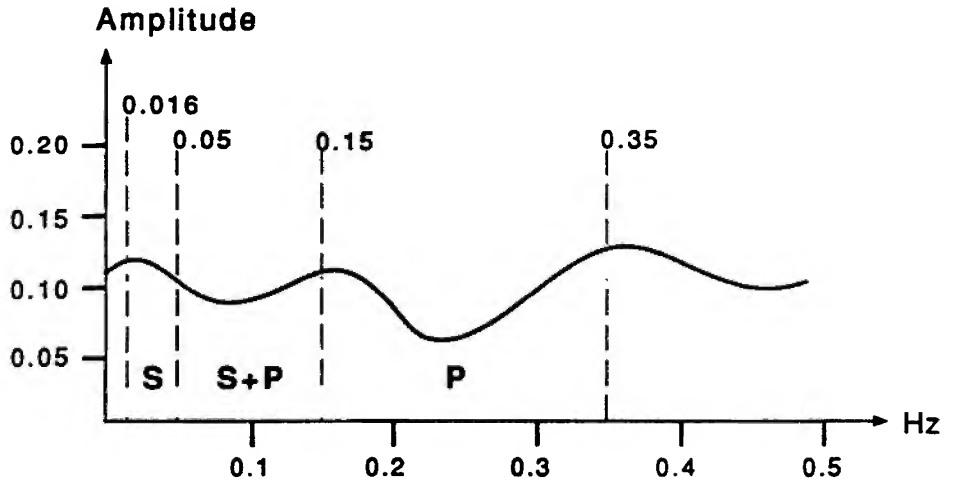
$$\frac{1}{2 * (\text{average RR interval})}$$

For frequencies above 0.15Hz, the influence from the sympathetic nerve on RR variability is neglectable.

The frequency spectrum in this high frequency range is mainly determined by the activity of the parasympathetic nerve. Between 0.05Hz and 0.15Hz, parasympathetic and sympathetic influences may be found.

Below 0.05Hz, influence of the parasympathetic nerve is significantly weaker than in high frequencies, whereas the sympathetic influence reaches its highest extent in low frequency ranges. An inhibition of the parasympathetic nerve therefore shows in a reduction of high frequency spectral ranges.

The following illustration shows a simplified presentation of frequency dependent effects by sympathetic (S) and parasympathetic (P) nerves.



Within these three frequency intervals (S, S+P and P), influences of sympathetic and parasympathetic may be assessed from the area (integrals) of the FFT spectrum.

These areas are indicated with the data from Ⓓ as percentage values with respect to the total area of the FFT spectrum:

Int. 0.016 to 0.05Hz	(Frequency interval S)
Int. 0.05 to 0.15Hz	(Frequency interval S+P)
Int. 0.15 to 0.35Hz	(Frequency interval P)

NOTE *In comparing data from various patients, percentage indications should be compared - **not** the absolute values, as spectral energy depends upon the individual patient.*

Furthermore at Ⓓ the selected window type (rectangular, Hanning, Blackman-Harris) is indicated, as well as the mode of the FFT calculation (1 to 4).

ATTENTION: *Age dependent standard values for RR variability have up to present not been considered neither in time nor in frequency analysis.*

Frequency Analysis

Signals in the Frequency and Time Range

A cosine signal in time domain is characterised by its amplitude A_1 and the time interval T_1 between two maximal values (period of oscillation T_1) (Fig 1a).

This signal acn önot only be presented in time domain, but also in the frequency domain. Frequency f is defined as indirectly proportional to time t: $f = {}^1/t$.

The cosine signal in frequency domain is therefore presented as (delta) peak with amplitude A_1 and frequency ${}^1/T_1$ (Fig 1b).

The cosine signal with a lower amplitude A_2 and a shorter period of oscillation T_2 (Fig 2a) is shown in frequency domain as peak with frequency ${}^1/T_2$ ($A_1 > A_2$, $T_1 > T_2$ and ${}^1/T_1 < {}^1/T_2$) (Fig 2b).

When both signals are summed (Fig 3a), two spectral lines result at the points ${}^1/T_1$ and ${}^1/T_2$ (Fig 3b).

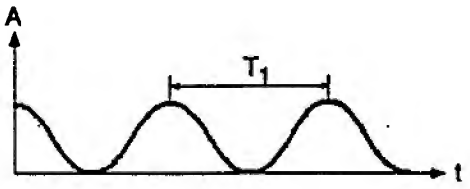


Fig. 1a
Cosine signal in the time

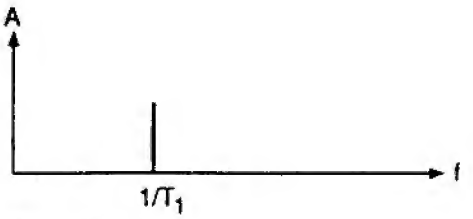


Fig. 1b
and frequency domain

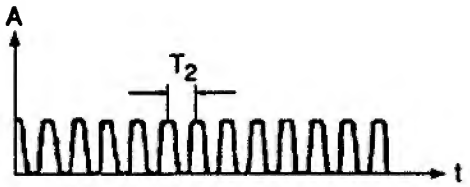


Fig. 2a
Cosine signal in the time

Fig. 2b
and frequency domain

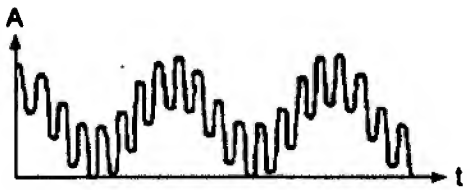


Fig. 3a
Sum of the signals of Fig.1 and Fig. 2 in the time

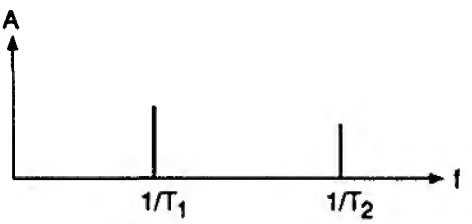


Fig. 3b
and frequency domain

Transformation from Frequency to Time Domain

The Fourier Transformation

Every arbitrary signal may be presented not only within time, but also within frequency domain, i.e. as sum of various cosine functions with different amplitudes (**Fig 4a/b**).

A transformation from time to frequency domain is performed by means of the so-called Fourier Transformation.

Fig. 4a

Arbitrary signal in the time

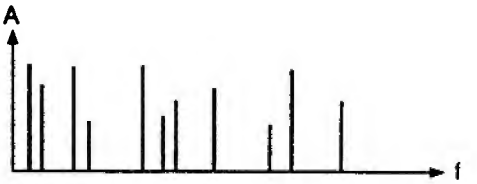


Fig. 4b

and frequency domain

A fast type of the Fourier Transformation is the so-called Fast Fourier Transformation (FFT), that calculates a Fourier Transformation with a number of sample values corresponding to a power of 2. In order to perform FFT, SCHILLER analysis examines either $512 = 2^9$ or $1024 = 2^{10}$ RR intervals.

Performance of the Fourier Transformation

Some signal characteristics are easier to detect in frequency than in time domain. Examinations on oscillation characteristics of motors are e.g. performed with Fourier Transformation, as indications of wear can be detected at an early stage from changes in the Fourier spectrum.

Furthermore, **pathological changes of the heart** can be detected in Fourier Transformation of RR intervals.

In practice no endless periodical signals are examined (**Fig 5a/b**), but time limited non-periodical signals (**Fig 6a**). Fourier Transformation of these time limited signals does not provide individual delta peaks as described above, but blurred peaks decreasing in an oscillatory manner to the right and to the left, producing the so-called sidelobes (**Fig 6b**).

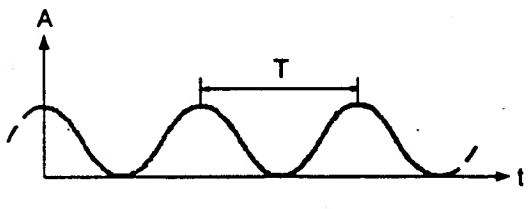


Fig. 5a

Endless periodical signal in the time

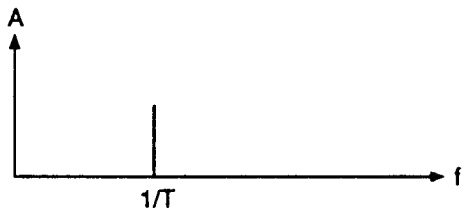


Fig. 5b

and frequency domain

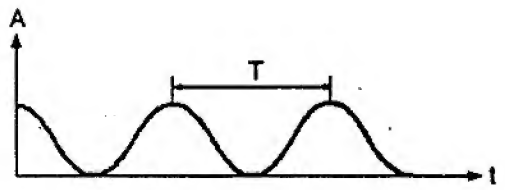


Fig. 6a

Time limited signal in the time

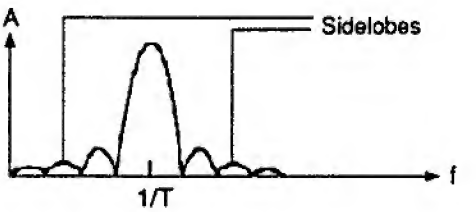


Fig. 6b

and frequency domain

Time Limitation of Signals (Windowing)

Usual time limitation (i.e. full signal amplitude up to the point of limitation, otherwise signal amplitude equals zero) can be imagined as windowing of an endless signal (Fig 7a) with a rectangle function (Fig 7b), speaking of a rectangular window function.

Endless periodical signal superimposed with a rectangular window

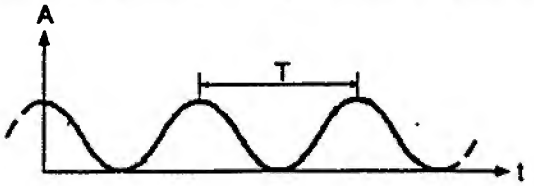


Fig. 7a

An endless periodical signal superimposed

Fig. 7b

with a rectangular window

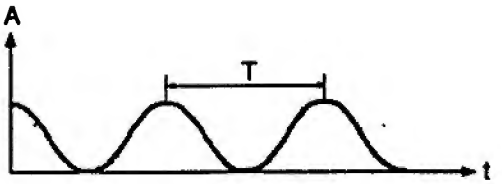


Fig. 8a

results in a time limited signal in the time

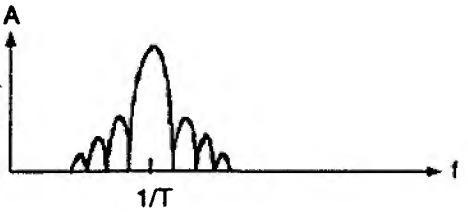


Fig. 8b

and frequency domain.

Such a rectangular window function, however, produces sidelobes with relatively high amplitudes (Fig 8b).

Optimal Window Types

Cutting off the signal not abruptly, but gradually, e.g. by windowing the signal with a cosine-like function (Fig 9b), provides side lobes with lower amplitudes, but extended main lobes (Fig 10b), as compared to the rectangular window type.

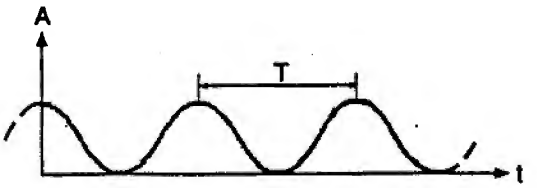


Fig. 9a

An endless periodical signal superimposed

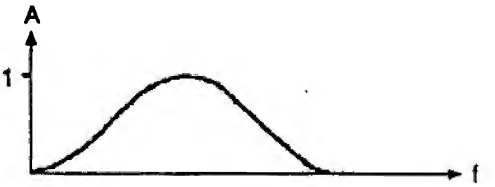


Fig. 9b

with a cosine window

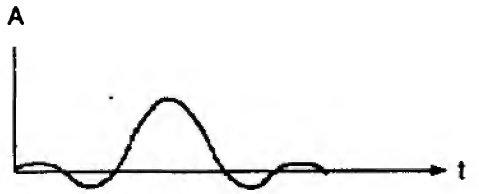


Fig. 10a

results in a time limited signal in the time

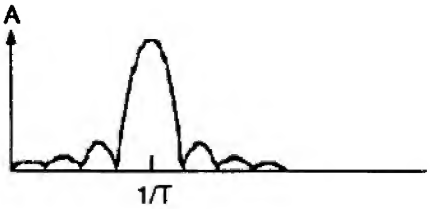


Fig. 10b

and frequency domain.

Optimal window types, minimising the disadvantages of high sidelobes and extended main lobes, are the cosine-like **Hanning** and **Blackman-Harris** window types.

Standardisation

Before performing Fourier Transformation of RR intervals, they are standardized according to different procedures. Calculation mode performed is determined in the menu "Heart Rate Variability", item "FFT Type".

For:

x(i) = value x, calculated from the *ith* RR interval submitted to FFT

RR(i) = *ith* RR interval

RRaverage = average RR interval

(1/RR)average = average calculated from the reciprocal values 1/RR of RR intervals

RR intervals are transformed as follows :

1. $x(i) = \dfrac{RR(i) - RRaverage}{RRaverage}$

2. $x(i) = RR(i) - RRaverage$

3. $x(i) = \dfrac{1/RR(i) - (1/RR)average}{(1/RR)average}$

4. $x(i) = 1/RR(i) - (1/RR)average$

Fourier Transformation is finally applied to the values x(i), and their FFT spectra are analysed within various frequency ranges.

Analysed Ranges

The FFT spectra are analysed within the following frequency ranges:

0.016 Hz to 0.05Hz,

0.05Hz to 0.15Hz

0.15Hz to 0.35Hz.

A reduced influence of the parasympathetic nerve can be detected on a reduction of the high frequency signal portion, whereas an increased influence of the sympathetic nerve results in an increase of the low frequency signal portion.

Both variations in the autonomous nervous system may influence electrical stimulation conduction within the heart, resulting in **an increased risk of continuous tachycardia and sudden cardiac death.**

Phase-space Plots

In addition to the statistical analysis of the RR-variability (such as the calculation of a mean value, standard deviation, absolute deviation, RR-tachogram and RR-histogram) and the frequency analysis (FFT analysis with 512 or 1024 RR intervals with selectable window types and standardization procedures), the program offers the **phase-space plots** as a further evaluation form of the RR variability. This analysis also considers, for the first time, the chaotic property of the heart.

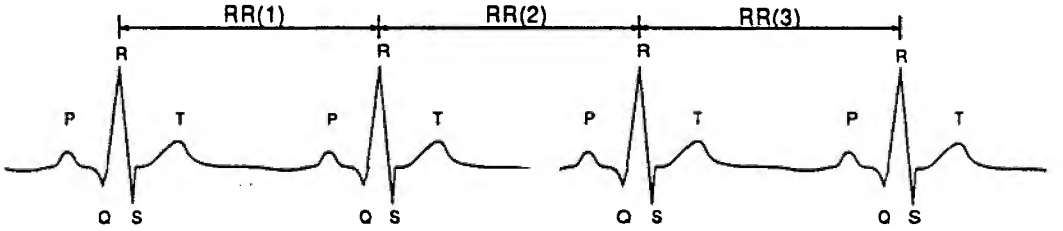
In the exploration of heart rate variability it has been indicated that mathematical methods of chaos theory considered for heart rhythm give further evidence of high risk of sudden cardiac death.

In this chaos theory (of deterministic chaos), complex systems with many interacting components are analysed. The interaction is non-linear, i.e. the change that a component effects, does not have to have the same size-order as the component itself. In other words: small changes in one component can effect very large changes in the system.

According to the latest studies, the heart, being a complex of many varying cells with its multiple influences from the central nerve system, reacts as a non-linear chaotic system.

The Fundamental Calculation of the Phase-space Plots

In the phase-space plot of the heart rate variability, the chaotic aspect of the heart rhythm is considered. Therefore you look at successive RR intervals during sinus rhythm:



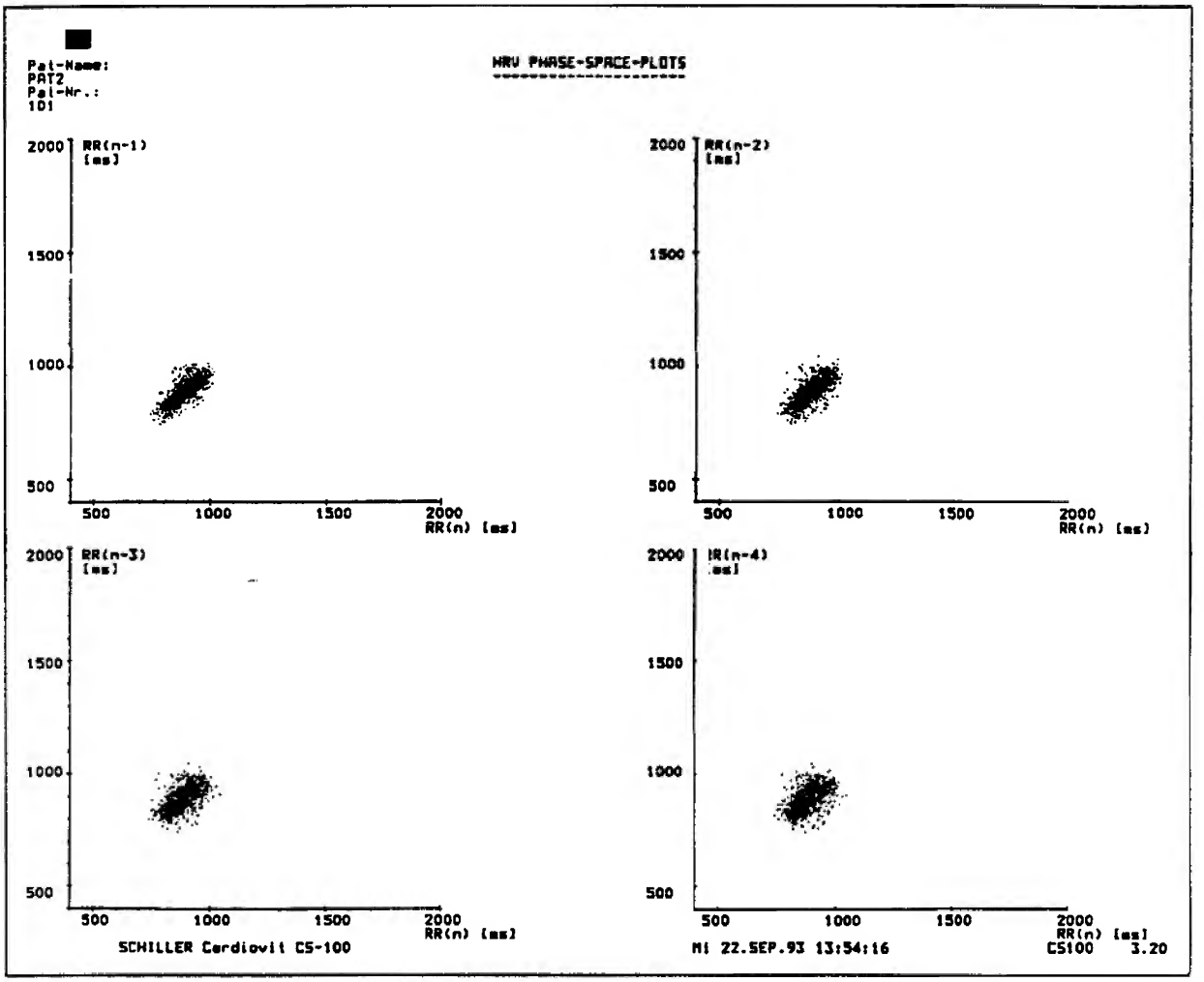
RR(1) is the first RR interval (between the first and the second R peak)

RR(2) is the second RR interval (between the second and the third R peak)

RR(3) is the third RR interval (between the third and the fourth R peak).

Phase-space Diagram - Printout

The phase-space plot being the second page of the RR variability evaluation looks as follows:



Phase diagram of a person with a healthy heart

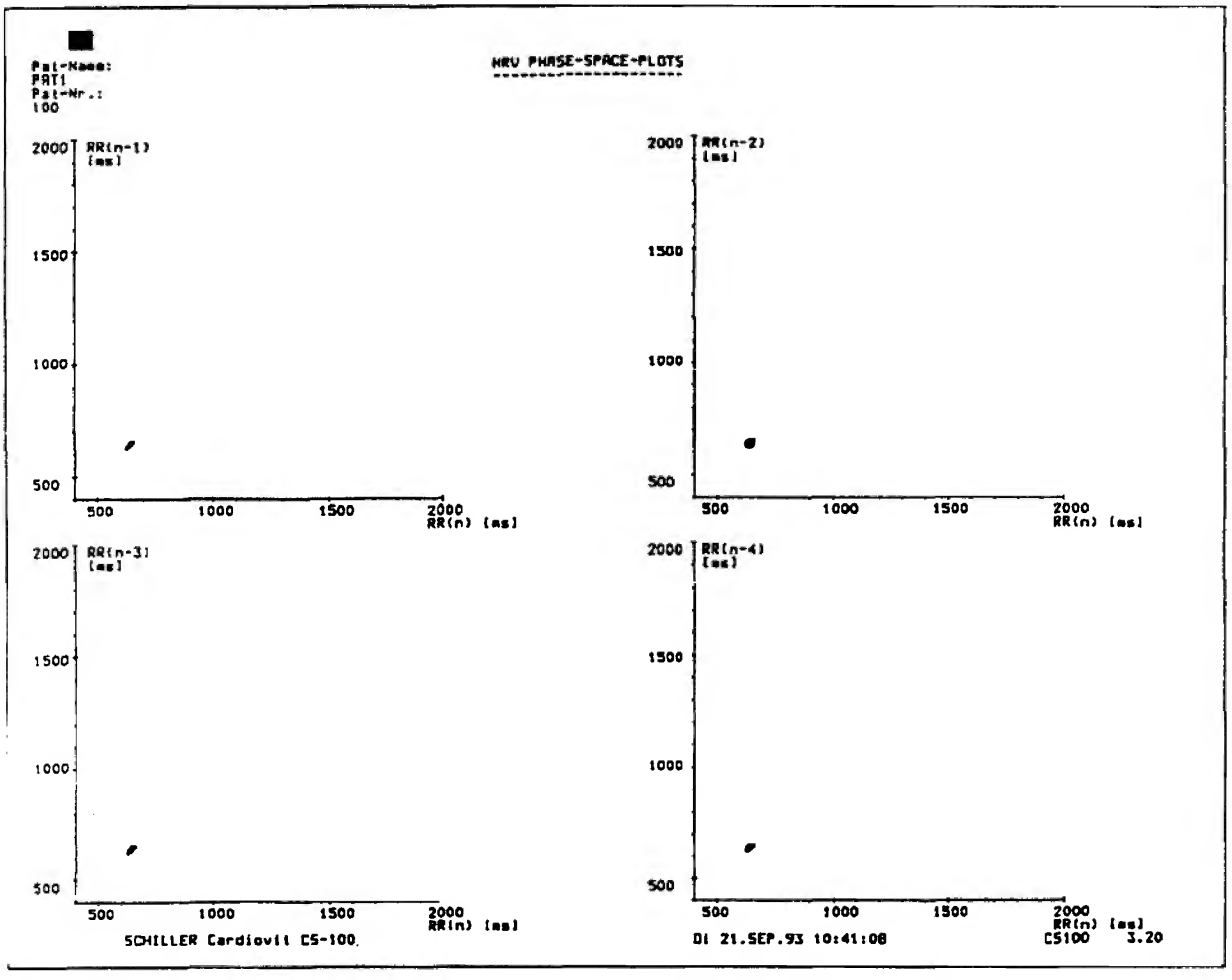
In the two-dimensional phase diagram, RR(2) is shown as the x-component and RR(1) is shown as the y-component of point (RR(2), RR(1)). The next point shows as x-coordinate RR(3) and as y-component RR(2). Generally the nth RR interval is represented on the x-axis and the (n-1)-th RR interval on the y-axis.

The phase diagram **top left** shows the correlation in rhythm between successive RR intervals. On the **top right** there is the correlation between one RR interval to the RR interval after the next (i.e. a distance of two RR intervals), **bottom left** shows the correlation between RR intervals that are three RR intervals apart and on the **bottom right**, there is the correlation of RR intervals with a distance of four RR intervals.

The total of all possible phase diagrams (endless!) forms the so-called multiple-dimensional phase-space diagram. The described representation only gives a fraction of this phase space.

The shape of these point-like clouds gives, according to latest studies, probably a standard for a patient's risk of sudden cardiac death. The above figure shows the phase diagram of a person with a healthy heart. In the cigar-shaped point-like clouds of a healthy person, one can see that this heart moves (within certain limits) between larger and smaller RR intervals, thereby reacting to physiological changes in the body.

The following phase spot plots of a patient with coronary artery disease shows a rigid heart rhythm. This patient has a very high risk of a sudden cardiac death. His heart cannot adapt to physiological changes in the body and therefore it is more likely to "completely loose its rhythm" under certain conditions, causing ventricular fibrillation and sudden cardiac death.

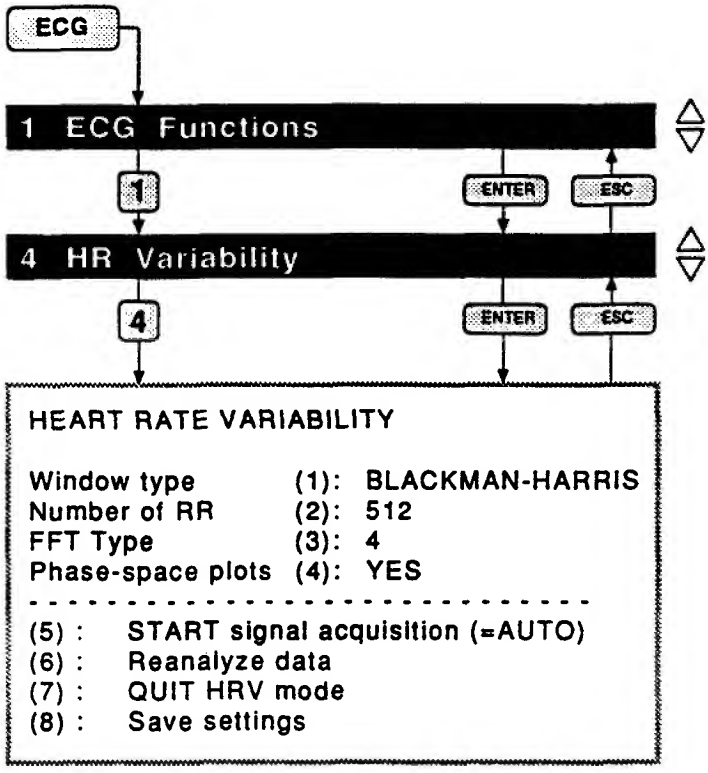


Phase diagram of a person with coronary artery disease

How far certain patterns in the phase-space plot can identify patients with a very high risk of sudden cardiac death, will have to be determined in further studies. Further mathematical analyses (such as dimension determination of the attractor in the phase space) will supplement graphic representation of the phase space in the future, and enable exact statements about the risk of a sudden cardiac death and about therapy effects.

Execution of the RR Analysis

To measure the heart rate variability, press the following keys:



To activate the analysis program proceed as follows:

1. Make following selections in the menu:
   - **Window Type**: (1): Select between: RECTANGULAR, HANNING, BLACKMAN-HARRIS
     Key **1** selects the window type.
   - **Number of RR**: (2): Select between: 512, 1024
     Key **2** selects the number of RR intervals to be analysed.
   - **FFT type**: (3): Select from: 1 to 4
     Key **3** selects the calculation mode for the fourier transformation.
   - **Phase-space plots**: (4): Set to YES or NO
     Select YES to printout the phase space diagram or NO to suppress the printout.
2. Start the signal acquisition by pressing key **5**.
   During signal acquisition, the number of intervals accepted for the analysis is displayed in the upper part of the screen.

   Once the predefined number of RR intervals has been evaluated for analysis, the printout is initiated.

As long as the data is in the memory, different window types can be selected for further calculations. Select a new window type (press key **1** for **Window Type**) and press key **6** (Reanalyze data). The results of this analysis will be printed out.

With the key **7**, the RR variability program can be quit without any printout.

To save the settings made, press key **8**.

Option 10

Floppy Disk Drive

CONTENTS

INTRODUCTION

According to your needs your EGC unit may optionally be equipped with a floppy disk drive.

- The floppies to be used are 3.5" diskettes (1.44MB capacity). Up to 220 ECGs can be stored on one floppy (depending upon the selected data, for instance approx. 70 resting ECGs comprising unprocessed data from 12 standard leads of 10 seconds duration with patient data).

Apart from ECGs, you can also store results from late potential and heart rate variability analysis as well as spirometry data.

You can retrieve stored data of a particular patient either for data transmission to a remote unit or computer via the serial interface or for a printing the data.

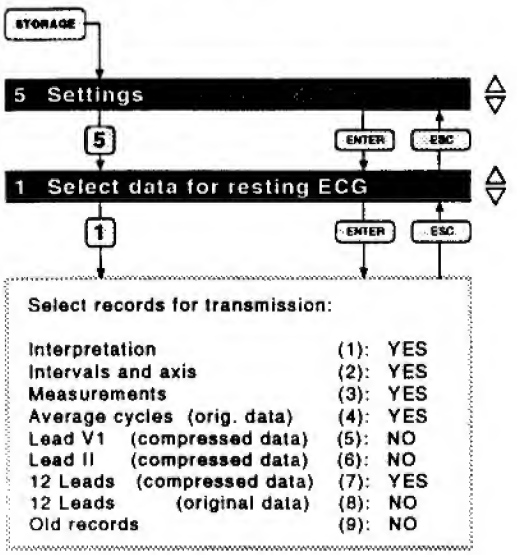
SETTINGS FOR STORAGE

There are two settings which apply to data storage. They need to be made before starting to store any data:

- Selecting the data to be stored
- Selecting the automatic storage function
  This function permits to store ECGs automatically.

Select Resting ECG Data

Press the following keys:



→ With the keys **1...8** select the data that you wish to store. The options are YES to select or NO to suppress.

NOTE:
Selections "5" and "6" are the programmed rhythm leads R1 and R2.

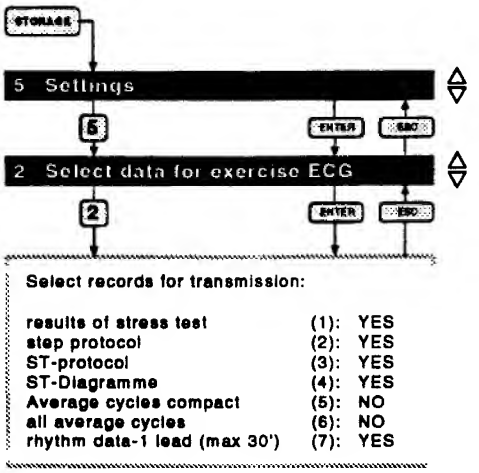
→ When the "12 leads (original data)" option is selected (selection **8**), only the original data is transmitted/stored and the selections 1 to 7 are suppressed.

→ When the "Old records" option is selected (selection **9**), the **original SCHILLER format** (raw data) is transmitted/stored and the selections 1 to 8 are suppressed.

NOTE:
The above example shows the typical settings that could be used for sending data to SEMA – SCHILLER's data management system on PC. Note that the '12 leads (compressed data)' option needs to be selected here.

Select Exercise ECG Data

Press the following keys:



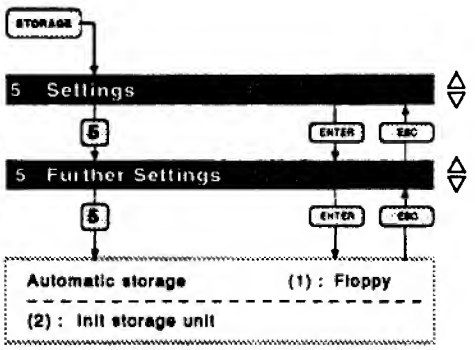
➜ With the keys **1...7** select the data that you wish to store. The options are YES to select or NO to suppress.

NOTE:
Selection 7 ' rhythm data - 1 lead (max. 30')' is the programmed rhythm lead R1.

Select Automatic/Manual Storage

If you always want the recorded data to be stored automatically, use the automatic function. This setting also permits to transmit data automatically to another unit. If you want to store or transmit data whenever the need arises, then ensure that the automatic function is disabled.

Press the following keys:



➜ Press key **1** and set to **"Floppy "** if you want the recorded data to be **stored automatically.**

➜ Press key **1** and set to **"Send"** if you want the recorded data to be **transmitted automatically.**

Set to **"NO"** to disable the function and to select **manual storage or transmission** (detailed information for data transmission is given in the "User Guide" of your ECG unit.

DATA STORAGE

Data storage permits to store the recorded ECG data on a floppy disk. For fast and easy retrieval, all stored data are presented in a list (see "Managing your ECGs " later in this chapter).

Data storage is different for resting and exercise ECG recording:

- With **resting ECG**:
  Manual or automatic data storage after ECG recording.
- With **exercise ECG**:
  Manual data storage of the last performed ECG recording.

NOTE:
*Exercise ECGs can only be stored manually after the final report has been printed out. Also note that the **EXEC option is required**.*

Preconditions for Data Storage

There are a few preconditions for data storage on floppy disk:

- Your floppy disks must be **3½" diskettes** with a storage capacity of **1,4 MB**.
- On your floppy disks the **write protection** must be disabled.
- Your floppy disks must be **formatted** (initialisation of the storage medium for accepting data).

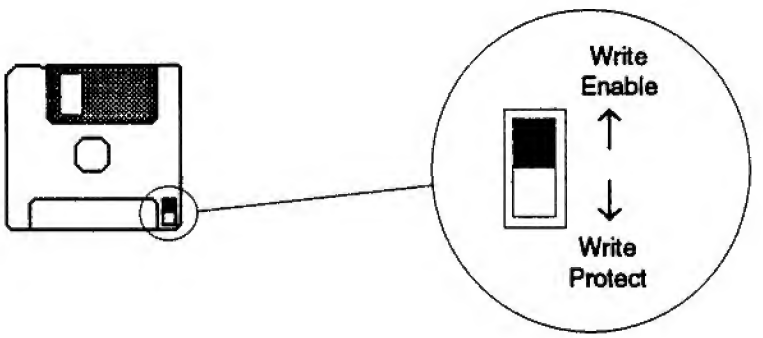
Handling of Floppy Disks

Some simple rules have to be considered when writing data to a floppy disk or reading data from it:

Write protection

The write protection in form of a slide is situated in a corner of the floppy disk (on the unlabelled side). Press the slide in the direction to have a transparent hole.
In this state no data can be written to the floppy (its content is protected against erasing).

To enable writing, press the slide in the opposite direction (no transparent hole), the slide must be locked in place.



Insert floppy

Insert the floppy into the slot of the floppy disk drive (label looking upwards and metal part towards the slot) until it is locked and the eject button jumps out.

Eject floppy

Press the eject button on the floppy disk drive. The floppy is released and can be removed by hand.

Safe keeping

Floppy disks are protected from dust and mechanical damage by their protective sleeve. They should be stored at normal room temperature and humidity. To protect them from data loss it should be insured that they are not stored near to magnetic fields (e.g. transformers, loud-speakers).

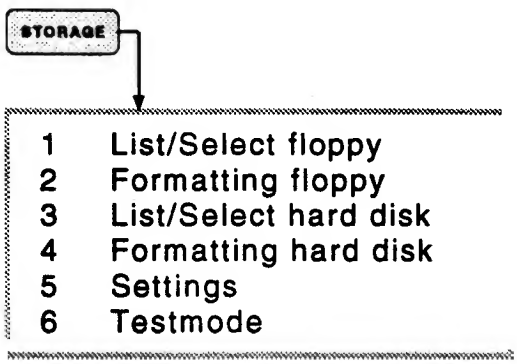
Formatting Floppy Disks

IMPORTANT:
Before using a new floppy the first time it must be formatted.

*The **floppy disk format** is identical with the format used with IBM compatible PCs for 3½" diskettes. Any 3½" diskette (1,4 MB) formatted on a PC can be used for data storage on your ECG unit.*

In case your floppy disk needs to be formatted, proceed as follows:

1. Insert the floppy into the floppy disk drive (writing enabled).
2. Press the key:



3. Use key **2** to format the floppy.

CAUTION!
Formatting erases all data !
To prevent data loss, the formatting must be confirmed:

Format floppy ? YES / NO

4. Confirm or prevent the formatting with the keys [NO] [YES].

The formatting procedure is indicated on the screen with the message "FORMATTING...". At the end the message "FORMATTING COMPLETED" is displayed together with an acoustic signal.

Error Messages with Formatting

See "Error Messages" later in this chapter.

Starting Data Storage

Preconditions for data storage:

- The storage medium must have enough free storage capacity.
  An indication of free storage capacity you will find in the list of stored data (second line from bottom, see "Managing your ECGs " later in this chapter). Note that a warning message is displayed when no more data can be stored on the storage medium. If this happens, delete files no longer needed as described in "Managing your ECGs".
- Before inserting the floppy disk be sure to have diasabled the write protection (transparent hole).

Manual Storage

Preconditions:

- The automatic storage function must be disabled (see "Select Automatic/Manual Storage" earlier in this chapter).
- ECG data must have been recorded and evaluated (key [AUTO START] for resting ECG, key [START] for exercise ECG).
- The ECG data to be stored must have been defined (see "Select Resting ECG Data" and "Select Exercise ECG Data" earlier in this chapter).

➜ Press the key [STORE DATA].

The storing procedure is indicated on the screen with the message "WRITING DATA...". At the end the message "DATA WRITTEN" is displayed together with an acoustic signal.

Automatic Storage

Preconditions:

- The automatic storage function must have been selected (see "Select Automatic/Manual Storage" earlier in this chapter).
- The ECG data to be stored must have been defined (see "Select Resting ECG Data" and "Select Exercise ECG Data" earlier in this chapter).

➜ When you press the key [AUTO START] the data are first evaluated and then stored.

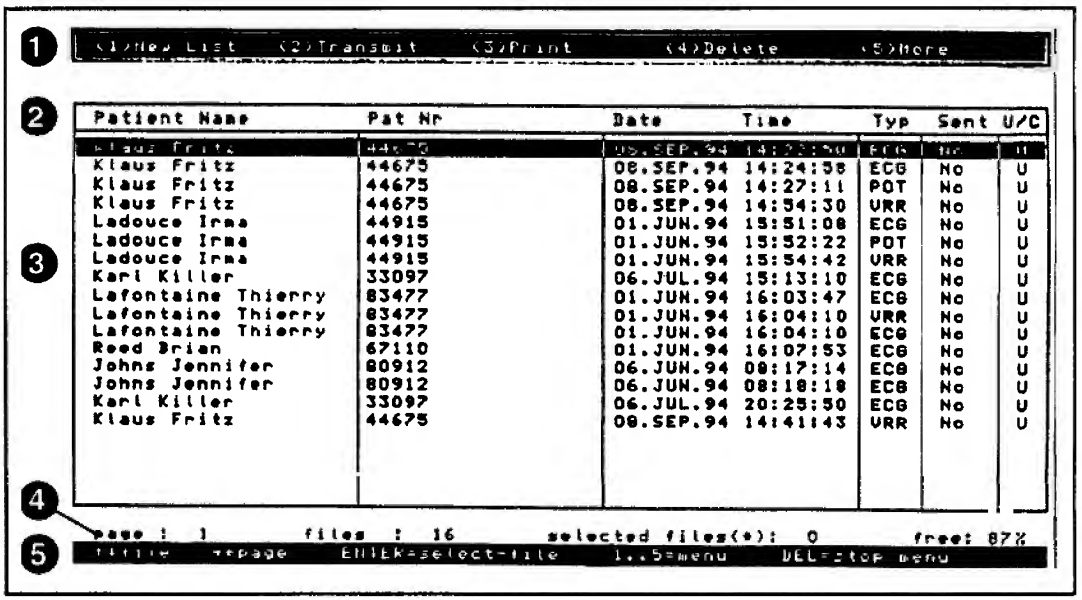
Error Messages with Storing

See "Error Messages" later in this chapter.

MANAGING YOUR ECGs

Your ECG unit automatically maintains a list of all data stored in the unit's storage medium which allows you to recall the data later as needed for printing or transmission. Files are identified by the patient's name and ID number plus the date and time that the data was recorded.

➜ Press the key [STORAGE] followed by key 1 (List/Select) to display the list of stored data. A display similar to the following will appear on the screen. When entering the list for the first time, the cursor is positioned on the first entry on page 1. Each time the list is entered again, the cursor will highlight the last selected file.



1 = Menu bar for selection

2 = List headings
- Patient Name, Pat Nr, Date, Time
- Type ECG = Resting ECG
  STR = Exercise ECG
  POT = Late Potential
  VRR = Heart Rate Variability
- Sent Yes/No = this indicates if an ECG was transmitted or not
- U/C Unconfirmed/Confirmed = Physician's comments (for future use)

3 = Listing of files

4 = Miscellaneous information
- Number of page currently displayed
- Total number of files stored
- Number of files selected
- Remaining storage capacity

5 = Information relative to the menus

When in the list proceed as follows to select file(s) for printing, transmission or deletion:

Select File(s)

➜ Only 20 files at a time can be shown on the screen. Use the directions keys [◁] [▷] to see the following or preceding page(s).

➜ Use the direction keys [▽] [△] to move the cursor to the desired file.

➜ By pressing key [ENTER] the selection will be marked with an asterisk (*) . Pressing this key again removes the asterisk.

Select Menu

Pressing keys **1 to 5** permits to select the desired menu for printing, transmitting or deleting selected file(s). When in a menu proceed as follows:

➜ Use the direction keys [◁] [▷] to move the cursor to a menu further right or left.

➜ Use the direction keys [▽] [△] to select the desired option from the menu selected.

➜ By pressing key [ENTER] you activate the function selected.

Menu Options

- **(1) NewList** updates the list of all data currently stored in the unit's internal memory

- **(2) Transmit** enables one or more patient files to be sent to another unit via the serial interface

  Select between

  – Transmit file(s) ..... transmits the file where the cursor is positioned or all files selected and marked with an asterisk (*). When updating the list , the indication **"Yes"** appears in the column "Sent" for the file(s) transmitted.

  – Transmit all files ..... transmits all files.

  – Transmit remaining files ..... selects all files for transmission which have not yet been sent , i.e. those marked with **"No "** in the column "Sent".

- **(3) Print** enables printout of one or more patient files on the printer in format 1

  Select between

  – Print file(s) ..... prints the file where the cursor is positioned or all files selected and marked with an asterisk (*).

  – Print all files ..... prints all files.

- **(4) Delete** enables one or more patient files to be erased (from list and memory)

  Select between

  – Delete file(s) ..... erases the file where the cursor is positioned or all files selected and marked with an asterisk (*) .

  – Delete all files ..... erases all files.

  – Delete sent files ..... erases all files sent to another unit (marked with **"Yes"** in the column "Sent".

  When erasing files, you are requested to answer the following prompt: File really delete? YES/NO (press keys [NO] [YES]).

- **(5) More**

  Select

  – Print file directory ..... prints a list (a directory) of all files.

Interrupting an operation

➜ Use the [STOP] key to stop printing of the file selected.

➜ By pressing [DELETE] you interrupt transmitting, printing or deleting of the files selected. The process stops at the point where a new file starts.

Returning to the list

To exit a menu and return to the list

➜ press key [ESC], or

➜ press key [DELETE], or

➜ select menu option NewList (key **1**, followed by [ENTER]).

ERROR MESSAGES

• DATA NOT VALID (92)	Data for storage/retrieval are not correct. This error message occurs during exercise testing when automatic storage/sending is activated. (Deactivate it with [STORAGE] – 5 – 5 – 1)
• SELECT DATA FOR ARCH.!! (=0) (98)	Data selection for resting or exercise ECG has not been done.
• DISK FULL (82)	Diskette full, new data cannot be stored. (delete records no longer needed by pressing the keys [STORAGE] – 1 – 4)
• DISK FULL (83)	as before
• DISK WRITE PROTECTED ? (92)	Ensure that the write protection is disabled.
• DISK WRITE PROTECTED ? (3B)	as before
• DISK EJECTED ? (36)	Diskette has been removed during floppy drive operation.
• DISK EJECTED ? (38)	as before
• DISK FORMATED ? (3A)	Diskette is not formatted, not readable or is not DOS-formatted. (format diskette).
• DISK CHANGE ! ! ! (85)	Diskette has been changed before the actual function was terminated (e.g. erasing).